

**In the Matter Of:**

**NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY**

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**VIDEOTAPED DEPOSITION OF DAVID A. KESSLER, M.D.**

*March 04, 2016*

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**NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY  
VIDEOTAPED DEPOSITION OF DAVID A. KESSLER, M.D. on 03/04/2016**

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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

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**IN RE: NEW ENGLAND  
COMPOUNDING PHARMACY, INC.  
PRODUCTS LIABILITY LITIGATION,**

**MDL No. 2419  
Master Dkt:  
1:13-md-02419-RWZ**

**THIS DOCUMENT RELATES TO:**

## All Actions

VIDEOTAPED DEPOSITION OF  
DAVID A. KESSLER, M.D.

9:00 a.m.  
March 4, 2016

Suite 2900  
275 Battery Street  
San Francisco, California

**GINA V. CARBONE, CSR #8249, RMR, CRR, CCRR**



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## A P P E A R A N C E S

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2

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8

9

10          **ALSO PRESENT: ALAN DIAS, videographer**

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DEPOSITION OF DAVID A. KESSLER, M.D.

EXAMINATION BY:

MR. GIDEON

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1                   **VIDEOTAPED DEPOSITION OF DAVID A. KESSLER, M.D.**  
2                    **MARCH 4, 2016**

3                   THE VIDEOGRAPHER: Good morning. We are on the  
4       video record at 9:00 a.m. Today is March 4th, 2016.  
5       This is a matter pending before the United States  
6       District Court for the District of Massachusetts, case  
7       No. MDL 2419.

8                   We are located today at 275 Battery Street, the  
9       city of San Francisco, California.

10                  My name is Alan Dias from Discovery Litigation  
11       Services.

12                  Counsel, would you please identify yourself for  
13       the record.

14                  MR. CHALOS: Mark Chalos for the plaintiff  
15       steering committee.

16                  MR. ARBITBLIT: Don Arbitblit for plaintiffs.

17                  MS. MARTIN: Annika Martin for the plaintiffs.

18                  MS. GENO: Ashley Geno for SSC and Dr. Lister.

19                  MS. MARTINEZ: Stacey Martinez on behalf of  
20       St. Thomas Health, St. Thomas West Hospital, and  
21       St. Thomas Network.

22                  MR. GIDEON: C.J. Gideon and Kaycee Weeter for  
23       Howell Allen, Saint Thomas Outpatient Neurosurgical  
24       Center, Debbie Schamberg, John Culclasure, SSC, Ken  
25       Lister.

1                   **THE VIDEOGRAPHER:** Will the court reporter  
2 please swear in the witness.

3  
4                   DAVID A. KESSLER, M.D.,  
5                   having been sworn, was  
6                   examined and testified as follows:

7  
8                   **EXAMINATION BY MR. GIDEON**

9                   MR. GIDEON: Is there something you wanted to  
10 say on the record before we got started?

11                  THE WITNESS: I do think we should -- I'd ask  
12 counsel to discuss the letter you received from the  
13 Department of Justice, and I would like that to be on  
14 the record and I'd like to address certain issues.

15                  MR. GIDEON: Okay.

16                  MR. ARBITBLIT: So, Counsel, we are getting  
17 copies made of the DOJ letter. We'd like it to be  
18 marked as an exhibit. And I wanted it to be on the  
19 record that counsel for the DOJ had asked us to instruct  
20 Dr. Kessler not to disclose any information that would  
21 waive any privilege that the government might have.

22                  We have not acknowledged that there is such a  
23 privilege, or that he might waive it, but we wanted the  
24 DOJ's position to be on the record. And if you have no  
25 objection, we'd have that letter marked as an exhibit.



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1 And we have copies for counsel.

2 MR. CHALOS: What's the exhibit number?

3 MS. WEEETER: 1232.

4 (Whereupon, Exhibit 1232 was marked for  
5 identification.)

6 MR. GIDEON: And, Don, you are referring to the  
7 letter we got yesterday from David Glass?

8 MR. ARBITBLIT: Yes. Dated March 3rd, 2016  
9 from David Glass, senior trial counsel.

10 And what we would ask, subject to your  
11 agreement, is that the deposition be shareable with  
12 counsel and their experts, but subject to an  
13 acknowledgment that we're going to give the DOJ a --  
14 some reasonable period, like ten days, to let us know if  
15 they have any problems or think that there's any issue  
16 they want to raise with the court.

17 If they don't find, the deposition becomes just  
18 a standard transcript. If they do, then the transcript,  
19 as previously mentioned, would be shareable with experts  
20 so that they would know what other experts are saying,  
21 but we would agree to keep it sealed until the court has  
22 a chance to rule on anything the DOJ might say.

23 Does that seem reasonable?

24 MR. GIDEON: I think it's already covered in  
25 the order -- the protective order in this case. My

1 understanding is all the depositions remain confidential  
2 for 30 days. Isn't that right, Mark?

3 MR. CHALOS: Yeah, I think that's right. But I  
4 think the only nuance here is that this would be a  
5 nonparty making an assertion of some kind of privilege,  
6 and I'm not sure that was contemplated by the original  
7 protective order.

8 MR. GIDEON: I don't think it was, but I will  
9 agree on behalf of my clients that we will treat this as  
10 confidential with the exception of giving it to our  
11 experts and clients for the next 30 days. And then if  
12 David Glass or somebody else has some criticisms or  
13 complaints, they can take it up in that time frame.

14 MR. ARBITBLIT: The other thing I wanted to  
15 mention is that Dr. Kessler has only reviewed documents  
16 that were available through the public record, either  
17 through the FDA's website or the response of the FDA  
18 through the Freedom of Information Act request. So  
19 there's nothing that he has from his tenure at FDA,  
20 which ended in 1997 before NECC was formed, and he has  
21 had no -- nothing in his FDA duties that had to do with  
22 the facts of this case.

23 MR. GIDEON: Okay. Did you want to say  
24 something?

25 THE WITNESS: To clarify, I'm not comfortable

1 with what you've agreed to. Let me just put a couple  
2 things and explain.

3 First, I would ask that you -- both of you or  
4 any lawyers in the room -- refrain from asking me  
5 anything that could be violative of the Department of  
6 Justice. So I would ask that you -- I don't have my  
7 counsel here. No reason for me to have counsel here.  
8 But I would ask you to put -- you know, you're the  
9 lawyers, so you do me a favor and not ask any questions  
10 that would cross the line with that letter.

11 Second, let me just put a couple things on the  
12 record. One, I was involved in no particular matter, I  
13 don't think NECC even existed, what was it 1998,  
14 something --

15 MR. GIDEON: Formed in '98.

16 THE WITNESS: '98. So I left, and I was not  
17 involved in any -- certainly not with regard to NECC.

18 MR. GIDEON: That's what Don just said.

19 THE WITNESS: And also nothing with regard to  
20 Saint Thomas during my tenure.

21 No. 2, I limited my opening report to FDA  
22 publicly available documents, best of my knowledge,  
23 right? Because there were things that were on the  
24 website, FDA, either congressional or FDA.

25 In the response -- in defendants' response



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1 exhibits, I did see certain FDA FOI documents. And  
2 while I'm a student, you know, I live the liberty of  
3 process issues, I'm not a scholar in that way and I  
4 certainly don't want to lawyer it. I do think there are  
5 issues if one -- as the DOJ letter stated -- if  
6 deliberative process is the decisional process that FDA  
7 made whether to do something or not do something. And  
8 to the extent that is protected, some of that FOI  
9 documents went toward those questions.

10 And I did respond in my supplemental, I mean,  
11 to the documents that defendants' experts raised. So I  
12 do think that they're -- I mean, if -- again, however  
13 the law of deliberative process and FOI, obviously we're  
14 dealing with exemption 5 here, I leave it to others.

15 I do ask, just to be respectful, that you  
16 really limit this. Because there's not counsel here  
17 representing Department of Justice, I do ask that you --  
18 I would like to limit this deposition to, you know,  
19 officers of the court. I mean, I only do that as a  
20 suggestion. It's up to you. But that would be my  
21 request until the DOJ -- because I certainly don't want  
22 to lawyer what's deliberative process and what's not.

23 MR. GIDEON: Well, what I'm willing to do on  
24 behalf of all my clients is to follow what I said just a  
25 few minutes ago. And that is to take the terms of the

1 existing protective order which makes the depositions  
2 confidential for 30 days and expand that to include the  
3 deposition of Dr. Kessler. That's as far as I'm willing  
4 to go.

5 The questions that I intend to ask today, in my  
6 judgment, do not intrude in any way on deliberative  
7 process of the FDA, and certainly not when Dr. Kessler  
8 was there, from 1990 to 1997. And he left in -- let's  
9 see. He left two years before the next one was  
10 appointed in '99.

11 What was the date of your departure from the  
12 FDA?

13 THE WITNESS: February '97.

14 MR. GIDEON: NECC was formed at the end of the  
15 year in 1998, so I really don't think it's a legitimate  
16 concern by David Glass. But we can address it on a  
17 one-to-one basis. We'll do a very orderly, respectful  
18 deposition today, and if something comes up, Don, I'll  
19 expect you to raise a hand. Okay?

20 MR. ARBITBLIT: Or the witness may.

21 MR. GIDEON: That's fine.

22 We also, I will tell you, Dr. Kessler, we have  
23 a magistrate judge that's very involved in the details  
24 of the case who can -- who will and can address these  
25 things quite well if an issue comes up.



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1 THE WITNESS: Great.

2 MR. GIDEON: Good enough?

3 MR. ARBITBLIT: Good enough.

4 I would just ask, when you say within the order  
5 that exists, I'm assuming that that means that you would  
6 like to share Dr. Kessler's deposition transcript with  
7 your experts.

8 MR. GIDEON: Yes.

9 MR. ARBITBLIT: And I respect that that's  
10 reasonable. I would ask whether you would consider  
11 giving DOJ the weekend to let us know before you  
12 circulate it.

13 MR. GIDEON: I'm not going to have it, Don, to  
14 circulate before the weekend is over anyway.

15 MR. ARBITBLIT: Well, you never know. I mean,  
16 court reporters are very responsive. When you ask them  
17 to expedite, they get their fingers working at warp  
18 speed and can get transcripts out quickly. And/or we  
19 could even get a rough for that purpose.

20 MR. GIDEON: I will agree to defer this until  
21 Monday morning if you want me to.

22 MR. ARBITBLIT: We'll send the rough to David  
23 Glass and tell him he's got the weekend.

24 MR. GIDEON: Okay.

25 THE WITNESS: Thank you very much, sir. I



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1 appreciate your consideration.

2 MR. GIDEON: Sure. Now my time starts at ten  
3 after 9:00. Good enough?

4 MR. ARBITBLIT: All right.

5 THE WITNESS: Thank you, sir.

6 MR. GIDEON: Should we get started?

7 THE WITNESS: I can't see you very well, would  
8 you mind pulling the curtain behind you? I'm squinting  
9 at you.

10 MR. GIDEON: What is it, the shining forehead?

11 THE WITNESS: No. It's the San Francisco haze.  
12 Thank you. Now I can see you, sir.

13 MR. GIDEON: Shall we swear the witness -- he  
14 already has been.

15 Q. Dr. Kessler, I know you've given depositions  
16 before, but let me give you three general rules that  
17 apply to this deposition today. If you will follow  
18 them, it will permit us to have a more informed  
19 discussion and will actually be much more efficient with  
20 your time.

21 First, please listen to the question I ask you.  
22 If at any time you do not understand what I'm asking,  
23 tell me and I'll do a better job the next time.

24 The second thing is, please give me a direct  
25 answer. And then if you need to explain a direct

1 answer, I won't cut you off.

2                 Third, if at any time you need to take a break  
3 as a matter of personal comfort, to check on family,  
4 somebody may be traveling, all I ask you to do is to  
5 finish the pending question, and then we'll take a  
6 break. It's not designed to be an endurance run.

7                 Good enough?

8                 A. Thank you, sir.

9                 Q. Sure. One of the things that I sent to the  
10 lawyers that engaged you is a Notice of Deposition.  
11 Have they provided you with a copy of it?

12                 A. Yes, I saw it. Yes.

13                 Q. All right. Let's get copies for everybody of  
14 Exhibit A.

15                 Exhibit 1233.

16                 (Whereupon, Exhibit 1233 was marked for  
17 identification.)

18                 MR. GIDEON: And what I would like to do is  
19 begin with Exhibit A that is attached to Exhibit 1233.  
20 Flip the page one more.

21                 You see that?

22                 A. Yes, sir.

23                 Q. Without me reading each of these individually,  
24 would you please tell me the materials you brought with  
25 you today.

1           A. Yes, sir.

2           So I have here on the table -- may I stand?

3           Q. Absolutely. Sure. Bring them back into the  
4 camera -- bring them back into the camera range.

5           A. Let me tell you --

6           Q. An oral inventory is okay.

7           A. And then we can go through them if you want to  
8 see that.

9           Q. Sure.

10          A. So I have binders on this table that represent,  
11 one, both my report and my rebuttal report. And the  
12 documents that are cited in each paragraph -- if there's  
13 a document cited in the paragraph or in a footnote, that  
14 document is behind that tab. So all the documents cited  
15 in both the report and the rebuttal report are in those  
16 binders.

17          Q. And there are how many binders?

18          A. Well, the ones that I'm referring to are the  
19 first three, I believe, if I can see that.

20          I then have a treatise on drug regulation by  
21 Don Beers. It's a publicly available treatise, if we  
22 want to refer to it, that I've looked at.

23          I have the defendants' experts reports.

24          Q. Which ones?

25          A. So I have Miller and Bradshaw.



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1 Q. Do you have any of the others?

2 A. So I have Mr. Penta's exhibits. I've not --  
3 the reason for that is that there were certain  
4 Massachusetts Board of Pharmacy documents, what I asked  
5 for, they were in that binder as referred to by  
6 Dr. Miller.

7 Q. Okay. The Penta exhibits, but not the Penta  
8 deposition?

9 A. That's correct. I mean, it was the exhibits  
10 that I looked at.

11 Q. Okay.

12 A. Okay? It was some of them.

13 In addition to that, there is, just a little  
14 beyond your question, and I have some others. There is  
15 an errata sheet. There are some typos, some numbers,  
16 that I think I've asked counsel to bring.

17 There are a few --

18 Q. Stop, please. An errata sheet to what?

19 A. I'm sorry. An errata sheet to my supplemental.  
20 There were a couple of typos in that.

21 Q. It's an errata sheet or a change to some of the  
22 content of your supplemental report?

23 A. Yes. So we brought that. Yes. Those are very  
24 minor.

25 Q. Are they just typos?

1           A. They're typos.

2           Q. Not substantive?

3           A. Nothing of substance. You can look at that.

4           Q. I will.

5           A. In addition, I asked counsel, there were some  
6 documents that I have looked at since the time I signed  
7 my report. So there's an additional list of things that  
8 I've looked at, and I asked counsel to do that.

9                 I asked counsel to bring a copy -- counsel has  
10 a copy of my invoice to give you.

11                 And then I have some documents in front of me  
12 here, sir.

13                 Q. Give me an inventory of what's to your left.

14                 A. So I have here bound copies of my report, I  
15 have my supplemental report, and I just have an index to  
16 my report --

17                 Q. Okay.

18                 A. -- of the schedules.

19                 Q. And what about the two other bound volumes at  
20 the bottom of that stack?

21                 A. So both of these are my report, sir.

22                 Q. Okay.

23                 A. Both of these are my report. I have some DOJ  
24 information on deliberative privilege from the DOJ  
25 website and others.



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1 Q. Okay.

2 A. So I have that.

3 Q. All right. Did you pull that last night after  
4 you saw the Glass letter?

5 A. Actually, I pulled it around 6:00 o'clock this  
6 morning.

7 Q. You have some kind of blotter in front of you  
8 too with a lot of handwriting on it. Is that yours or  
9 is that something that's here for the witness?

10 A. No, this is mine.

11 Q. It is?

12 A. Yes.

13 Q. And tell me what the blotter represents that's  
14 material to today's discussion.

15 A. You asked me for notes.

16 Q. Okay.

17 A. So I was being responsive to your request.

18 There are a couple of documents, GEO reports, excerpts  
19 from that, so these are notes you've asked me to bring.

20 Q. You are the first witness I've ever met that  
21 uses a blotter as a means of recording notations; is  
22 this something you made as you went through the  
23 materials?

24 A. Yes, sir.

25 Q. Is this your routine to use a desk blotter for



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1 that purpose?

2 A. I wouldn't want to say I use it all the time,  
3 but I've used it on numerous occasions. Yes.

4 Q. How many pages of content are there on the  
5 blotter?

6 A. One, two, three, there's some typed -- three --  
7 there's a little handwriting. Maybe five, sir.

8 Q. Okay. It's probably unfair to ask you this  
9 question, but is your handwriting -- is your handwriting  
10 decipherable or are you the typical physician who writes  
11 in his own little script?

12 A. You asked me to answer directly?

13 Q. I do.

14 A. Yeah. You can stand over my shoulder and help  
15 me answer that question whether you -- I mean, I can --  
16 well, I don't know if I can read it.

17 Q. Well, I'm sure you can. My God, I hope so.  
18 But let me look at it.

19 A. See if you can -- thank you, sir.

20 Q. Actually, you're better than the norm. But you  
21 kind of fall at the 50th percentile.

22 A. I'm sorry.

23 Q. We're going to have to get this copied and  
24 probably have you dictate it.

25 Is there an engineering firm nearby that can

1 copy those large pieces of paper, Don?

2 MR. ARBITBLIT: I can find out.

3 MR. GIDEON: Would you ask someone at a break  
4 just to check and see if there's an architectural or  
5 engineering firm around that can do that at my expense  
6 today?

7 MR. ARBITBLIT: I'll do it now.

8 MR. GIDEON: Okay.

9 Q. What I would like to do next --

10 A. Can I just continue one thing so I'm complete?

11 Q. Absolutely. Go ahead.

12 A. So I have some documents on the floor.

13 Q. Inventory them for me, please.

14 A. So these are documents that I have either --  
15 you asked me to bring documents, I mean, that I have  
16 looked at or collected. I'm happy to go through them,  
17 but you should know there are -- there are documents  
18 here.

19 Q. Dr. Kessler, have we now identified your entire  
20 file in conjunction with your engagement in this case?

21 A. Not exactly.

22 Q. Okay. What else do we have?

23 A. So I have a hard drive.

24 Q. Okay. That's on your laptop?

25 A. It's connected -- plugged in, but happy to give



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1 you the hard drive if you would like.

2 Q. Does the hard drive duplicate the materials  
3 that we've just talked about or does it expand beyond  
4 the materials you've identified?

5 A. I believe it expands beyond the materials, sir.

6 Q. Is there an index to the hard drive?

7 A. There are -- there are file names. If you  
8 would take those as an index, I guess I can give you the  
9 file names.

10 Q. Okay. All right. We have the hard drive, we  
11 have an additional list of materials that you have  
12 reviewed that you've asked the lawyers to give me today.

13 A. Yes, sir.

14 Q. We have an errata sheet for some nonsubstantive  
15 changes in your rebuttal report. We have the five pages  
16 of handwritten text on the blotter before you. We have  
17 some invoices you've asked the lawyers to produce for me  
18 today. And then we have the intangible data on the hard  
19 drive where there isn't a formal index, but there are  
20 separately noted file names.

21 And you can duplicate the hard drive for me?

22 A. I can't, but somebody, I'm sure --

23 Q. Someone else can?

24 A. Certainly happy to give this to someone.

25 Q. Now, I'll ask the same question again: With



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1       that description of materials, do we have a complete  
2       identification of your file for this engagement?

3           A. Yes, sir.

4           Q. All right. I asked also for an updated CV if  
5       the CV that was attached to the original report is  
6       incomplete. Do you have an updated CV?

7           A. I don't believe I've updated my CV, but I don't  
8       want to represent that that -- I don't think there is an  
9       updated CV. But I also don't want to represent that  
10      that CV is up to date. I mean, at a certain point I  
11      stop putting things on.

12          Q. Okay. I asked also for communication  
13       specifically between the attorneys for the plaintiffs  
14       and you that relate to compensation for your study or  
15       testimony. I know that you are charging a thousand  
16       dollars an hour, but I don't know what that is  
17       applicable to. Is that applicable to our discussion  
18       today?

19          A. So --

20          Q. Are you charging me a thousand an hour to talk  
21       to me today?

22          A. My rate is a thousand dollars an hour.

23          Q. Well, the reason I ask, some witnesses will  
24       charge \$250 to review materials, somewhat more for a  
25       deposition if there's no videotape, some ask for a

1 premium if there's a videotape, some ask for even more  
2 if they show up in court. Is yours a lump-sum thousand  
3 dollars an hour?

4 A. Yes, sir. It's been standard that way for a  
5 good five, six years.

6 Q. Okay. Then I also wanted you to identify the  
7 facts or data that the attorneys provided to you to be  
8 considered in forming your opinions, and I want to draw  
9 a distinction between what they gave you and what you  
10 selected. So will you do that for us, please.

11 MR. ARBITBLIT: I'll object to anything that  
12 invades the work product privilege. And -- let me  
13 finish.

14 MR. GIDEON: I'm not cutting you off.

15 MR. ARBITBLIT: You just looked like you were  
16 ready to speak, and so I just wanted to finish before  
17 you do.

18 Doctor -- we have provided nothing to  
19 Dr. Kessler other than documents in the litigation. We  
20 have not -- he has not relied on anything from counsel  
21 in terms of documentation of facts. And anything that  
22 we've provided in terms of communications is protected  
23 by the confidentiality under Rule 26.

24 MR. GIDEON: Revised Rule 26.

25 MR. ARBITBLIT: Revised Rule 26.

1                   MR. GIDEON: I'm fully familiar with the  
2 language.

3                   MR. ARBITBLIT: I just want to make sure. The  
4 witness isn't necessarily familiar with the distinction,  
5 Counsel, so I want to make sure that communications  
6 between counsel and the witness are confidential, and  
7 the only things that he's relied on are matters that are  
8 in the documentation or the transcripts.

9                   MR. GIDEON: Okay. Well, but there is -- there  
10 is no privilege, Don, there's no protection for tangible  
11 factual materials that have been given to a witness.

12                  MR. ARBITBLIT: And no such materials -- I'll  
13 represent to you that no such materials have been  
14 provided other than what's in the documentation that's  
15 been produced in the litigation.

16                  MR. GIDEON: That's been identified in the  
17 report?

18                  MR. ARBITBLIT: Correct.

19                  MR. GIDEON: Q. Okay. Now, then, with  
20 that representation, what I want to know is what did  
21 Dr. David Kessler pull on his own.

22                  A. We'd have to go through each document.

23                  Q. Just tell me which ones, by looking at them,  
24 you selected on your own.

25                  A. You say -- you mean selected -- tell me -- I'm

1 not sure I understand your question.

2 Q. You don't understand the word "selected on your  
3 own" or the phrase "selected on your own"?

4 A. No. Because let me tell you why I don't  
5 understand it, and maybe that will help you.

6 Q. Sure.

7 A. So as I understand it, there are documents  
8 relating to -- they were part of discovery in this  
9 matter. Right? I didn't do, for example, an FDA FOI  
10 request, okay. I don't know which party did. So I --  
11 did I select -- if I asked for documents, right, did  
12 that mean I selected -- if they gave me -- I don't have  
13 access to the database that you have, right?

14 So there are documents that I pulled off the  
15 website. There are documents I asked counsel for. We'd  
16 have to go through, you know, again, what you mean by  
17 "selected." Did I ask them for it? Did they give it to  
18 me? Did I get it from a separate -- depends what you  
19 mean by "selected."

20 Q. Okay. Well, this isn't designed to be as  
21 complicated as your response makes it sound.

22 A. I'm sorry.

23 Q. I'm not interested in repeating the things that  
24 were given to you by the lawyers that engaged you, which  
25 Don just told us are reflected in your reports. What I

1 am interested in are things that you decided you would  
2 pull from a website or ask for on your own.

3 A. There were many things that I asked for --  
4 again, I apologize. I just don't understand your  
5 question. I'm just being exact.

6 There are certainly things that went into my  
7 report that I asked for. Is that what you are asking  
8 for?

9 Q. Tell me what things you can recall asking those  
10 that engaged you to send to you.

11 A. Oh, okay. Well, we'd have to just start with  
12 the beginning of the report and go through the report.

13 Q. I don't want to spend the time going through  
14 the report. You can't tell me the things you asked for  
15 unless we go through the report paragraph by paragraph?

16 A. There are -- there are thousands of pages, I  
17 mean, that I now have available. I certainly don't --  
18 I'd have to go and refresh my memory. If you show me a  
19 document, I could tell you whether I asked for it.

20 Happy to do that.

21 Q. Okay. But what I would like to know is whether  
22 you recall asking for any particular documents. Or you  
23 can answer that question without the time-consuming  
24 process of going through the report page by page,  
25 paragraph by paragraph.

1           A. I asked for many documents.

2           Q. Can you recall any of those that you asked for?

3           A. Sure. I asked for documents of my testimony  
4 that I gave.

5           Q. In other cases?

6           A. No. I mean, on compounding.

7           Q. Uh-huh. The May 1, 1996 testimony to Congress?

8           A. I asked for that. I asked for compliance  
9 policy guides.

10          Q. The 2002 compliance policy guide and its  
11 predecessor?

12          A. Yes.

13          Q. Both of those?

14          A. Yes. I asked for documents -- publicly  
15 available documents with regard to -- to NECC. There  
16 was publicly available documents that I asked for, and  
17 then I saw FOI requests and then I asked for that.

18          Q. Okay.

19          A. I asked for depositions in this matter.

20          Q. And which ones did you receive?

21          A. So I received Schamberg.

22          Q. Debbie Schamberg?

23          A. Yeah.

24          Q. Did you receive John Culclasure's deposition?

25          A. I did. And also I also asked for the

1 exhibits.

2 Q. Any additional depositions?

3 A. Kelvas.

4 Q. Marty Kelvas, did you receive that?

5 A. And the exhibits.

6 Q. Did you ever receive a deposition taken of an  
7 individual whose name is Terry Grinder?

8 A. Yes, I did. Tennessee Board.

9 Q. Board of Pharmacy?

10 A. And the exhibits I asked for. Yes.

11 Q. Any additional depositions?

12 A. Carmen Leffler. And I think there was Regina  
13 Calishers.

14 Q. Okay. In terms of your note keeping as you  
15 review materials, aside from the blotter that's in front  
16 of you now, do you prepare memos or notes on a computer,  
17 iPad or smartphone device in addition?

18 A. No. I would tend to scribble.

19 Q. All right. What else do you recall asking for  
20 as part of this engagement?

21 A. So I asked for rules of STOPNC, medical staff  
22 rules, formularies of STOPNC. I asked for -- I asked  
23 for or pulled shortage lists from the American Society  
24 of Health System Pharmacists. I pulled -- I pulled or  
25 asked for articles on ESI. I asked for specific



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1 shortage information on MPA.

2 Q. Also limited to ASHP data or other databases?

3 A. I think there's FDA as well as ASHP.

4 Q. And when you say MPA, you mean

5 methylprednisolone acetate?

6 A. Exactly. And Depo-Medrol, both.

7 Q. Okay.

8 A. Because some include both.

9 Q. Did you ask for any data reflecting when Sandoz  
10 and Teva quit producing generic methylprednisolone  
11 acetate in the states?

12 A. I have some reference to the generic on the  
13 shortage list. And some shortage lists, I believe, talk  
14 about Teva --

15 Q. And Sandoz?

16 A. Yeah.

17 Q. Did you get that data as part of this?

18 A. I'm happy to show you what data. We can pull  
19 it out.

20 Q. Where is that, the stuff we're talking about  
21 now, the shortage list, the articles on ESI, data that  
22 may come from the FDA on production of MPA in the  
23 United States? Is that in a stack here?

24 A. You have it in my report.

25 Q. All right. It's reflected in the report



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1 itself?

2 A. So it's reflected in the report. And what I  
3 tried to do, if you have my report, you'll see there's  
4 extensive schedules. So that's -- these are an  
5 example -- I mean, all of those schedules. I mean,  
6 everything in the report. I mean, all those schedules  
7 are materials that I've asked for.

8 Q. Okay.

9 A. And I wanted us to have it available today if  
10 you want to ask me about it. So all that material.

11 Q. Okay. Continue with anything else that you, as  
12 the witness, asked the people that engaged you to send.

13 A. I asked for the prescriptions. Any  
14 prescriptions, prescription order forms. Those were  
15 included as exhibits in both Culclasure and Schamberg's  
16 deposition. So when I asked for the depositions, I got  
17 the exhibits. But I certainly asked for that.

18 Q. As part of the exhibits that were made  
19 available to you from the Penta deposition, were you  
20 given a copy of the October 2010 letter from NECC to the  
21 Massachusetts Board of Pharmacy sending them the order  
22 form that was used in these cases?

23 A. So there was reference to that. Yes. I don't  
24 remember -- there's reference to that in, I believe,  
25 Dr. Miller's report. There's a footnote to a document.

1       And I did, at one point, look at that.

2               I can tell you -- I also have a disc of Mr. --  
3       you'll see it on the hard drive -- of Mr. Bradshaw's  
4       exhibits. I can't tell you whether I saw that off of  
5       Bradshaw's exhibits or Penta's exhibits.

6       Q. Okay. All right. What else do you recall  
7       asking for, Dr. Kessler, other than what we've already  
8       talked about?

9       A. If you let me go through my report and refresh  
10      my memory.

11      Q. I don't want to spend the time going through  
12      this page by page.

13      A. Basically, if you look at my report and you  
14      look at the -- the supplemental report, and you look  
15      at -- I asked, for example, what was cited by  
16      Mr. Bradshaw and Dr. Miller. So I looked -- I asked for  
17      those documents.

18      Q. Did you overlap with Mr. Bradshaw at the FDA?

19      A. I believe he was 2005 to 2007, something like  
20      that.

21      Q. So the answer is no?

22      A. Are those his dates?

23      Q. Yes.

24      A. If those are his dates, the answer is no.

25      Q. And Dr. Miller you overlapped with, did you



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1 not?

2 A. I did.

3 Q. For what period of time? You were commissioner  
4 from sometime in 1990 until sometime in 1997?

5 A. I was confirmed around October --

6 Q. Of '90?

7 A. -- of '90. Didn't really start in the position  
8 until about December of 1990.

9 Q. Okay. December of '90? And when did you --

10 A. I mean, I was confirmed before then, but I  
11 think my start date was when I really arrived in office.

12 Q. When did you leave the FDA?

13 A. February '97.

14 Q. What date, though?

15 A. I'd have -- we'd have to go look.

16 Q. You don't know the precise date?

17 A. I think -- I think it was the last day of  
18 February, but don't hold me to it.

19 Q. Okay.

20 A. It was a White House event for me and it's a  
21 matter of public record.

22 Q. Did you sign an NDA as you left?

23 A. I have no recollection, but I think I would  
24 remember that. I don't think that was practiced at the  
25 time. It was practiced at the agency. There are laws

1 governing, right, I mean, post employee conduct. I'm  
2 aware of those. But I'm not aware of any nondisclosure.

3 Q. All right. Okay. And your overlap with  
4 Dr. Miller who was head of one of the divisions of the  
5 FDA for a number of years was how long?

6 A. That's actually not correct.

7 Q. It's not?

8 A. It was an office of biotechnology, it was not a  
9 division. I don't mean to be quibbling. But I believe  
10 he was an office in the commissioner's office.

11 Q. What was the overlap is the key. How many  
12 years together?

13 A. I think he was -- I think he left -- you'd have  
14 to ask Dr. Miller when he left. I actually probably  
15 have it on his CV. Was it '94 or something? He's  
16 certainly out by '95, because I have documents here  
17 concerning Dr. Miller in 1995 that I have in my pile  
18 below me.

19 Q. Did the person who filled the head of the  
20 office of biotechnology serve at the pleasure of the  
21 commissioner?

22 A. The only one -- the only one who gets to use  
23 that term, sir, is the president of the United States.

24 Q. Well, I need to ask the question and get a  
25 direct answer. What's your understanding. As the



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1 commissioner of the FDA, who can you select and who can  
2 you terminate --

3 A. So --

4 Q. -- without having to get somebody else's  
5 permission, whether it's political or not?

6 A. It's a complex answer to that question.

7 Q. You can't fire the head of the office of  
8 biotechnology --

9 A. Um.

10 Q. -- as the commissioner of the FDA?

11 A. I didn't say that. Usually, I mean, there's --  
12 there's agency personnel offices, and it depends on  
13 one's status. Political appointees, my guess, probably  
14 would be fired by the White House, right, probably after  
15 consultation with the commissioner and the secretary, if  
16 that were the case.

17 Career civil service would be handled by human  
18 resources or the personnel office in consultation with  
19 management, but personnel would take care of it.

20 Q. All right. Well, let me ask the question  
21 again. Based on your understanding of the authority of  
22 the commissioner's office at the FDA, were you able to  
23 select who you wanted to head the office of  
24 biotechnology without having to get anybody else's  
25 permission or approval?

1           A. No. It never works that way in government.  
2 Any appointment that I would make would be subject,  
3 again, to the personnel office's civil service regs.  
4 That processes, those individuals, and any political  
5 appointment would be made at the White House level of  
6 presidential personnel.

7           Q. So was Dr. Miller appointed to head up the  
8 office of biotechnology by a president of the  
9 United States?

10          A. The -- what was Dr. Miller's status? Was he a  
11 presidential appointee?

12          Q. That's what I'm asking you.

13          A. So Dr. Miller was not a presidential appointee,  
14 because there is no other presidential appointee at FDA.  
15 Was he a political appointee, I don't know. Dr. Miller  
16 was there before I got there.

17          Q. Okay.

18          A. And Frank Young hired him.

19          Q. I missed the last name. Frank who?

20          A. Frank Young worked with personnel to bring --  
21 but I have no idea how Dr. Miller was brought on board.

22          Q. Did you bring any literature that you've relied  
23 upon in performing the opinions expressed in your  
24 report? And by that I mean any peer reviewed published  
25 literature, whether it's in a treatise or a quarterly or

1 monthly publication. Do you have that with you today?

2 A. Sure. So I did mention, for example, I brought  
3 the Beers treatise on drug regulation.

4 Q. Correct.

5 A. And I think that --

6 Q. Is that it?

7 A. I brought that. I have other documents here  
8 that we can go through if you would like.

9 Q. Let me see those, please.

10 A. May I just grab something to drink?

11 Q. Absolutely. Certainly.

12 MR. ARBITBLIT: Counsel, Dr. Kessler gave me a  
13 few items that he wanted copied yesterday to provide in  
14 response to the notice that I was given this morning.  
15 So they're not in his pile, but I want to make sure you  
16 are aware of them.

17 MR. GIDEON: Let me have them, please.

18 MR. ARBITBLIT: I don't have as many copies.

19 THE WITNESS: I may have a copy.

20 MR. ARBITBLIT: Well, this is one of them.

21 Here's copies for the --

22 THE WITNESS: I think I have those in my pile.

23 MR. ARBITBLIT: It may be that you have those.

24 C.J., I have these two articles. Why don't you  
25 take a look at these and see if you already have them in

1 the stack. If you do, you can give those back to me or  
2 have them marked as exhibits, as you choose.

3 MR. GIDEON: This one I do have in the stack.  
4 I haven't seen the second one yet.

5 THE WITNESS: It may be behind the first.

6 MR. GIDEON: Yeah. I've got this one. Thank  
7 you.

8 Q. Okay. Dr. Kessler, I appreciate you giving me  
9 these materials, and I'm going to do a quick inventory  
10 of these before I hand them back to you. But what I'm  
11 actually very specifically interested in right now is  
12 published literature, whether it's a treatise, textbook,  
13 New England Journal of Medicine article.

14 Now, in this group there is an article from the  
15 Pharmacist that's dated November 16th, 2011 entitled,  
16 "FDA Tries to Compound the Compounding Rules."

17 And likewise, in this stack of materials, is  
18 another article from the Pharmacist entitled, "The FDA  
19 Mandate: Never Give Up, Never," publication November  
20 22nd, 2006.

21 Other than that, I don't see any literature  
22 like I was thinking of in this stack.

23 A. Let me see it. I think I understand your  
24 question a little better.

25 Q. Sure.

1           A. If you turn to Appendix C of my report.

2           Q. Okay.

3           A. You will see long lists of, I think, the  
4 materials you -- for example, textbooks, other  
5 documents. They are all cited in my report or in the  
6 appendix, and they are footnoted. And I do have copies  
7 of them in my binders and I have copies of them here.  
8 So, I mean, for all the opinions --

9           Q. To save time --

10          A. I'm sorry.

11          Q. Let's make sure -- I've read your report over  
12 and over and over again. I've read the articles as  
13 well. What I'm interested in, is there anything else  
14 that you have pulled, looked at, considered this morning  
15 at 6:00 a.m., that's not listed in the bibliographies  
16 that you consider to be reliable or authoritative  
17 published material? That's the essence of the question.

18          A. I think we've discussed everything. I mean,  
19 it's the material that I have with me today --

20          Q. All right.

21          A. -- or on hard drive. I mean, or in these  
22 binders. Everything -- I tried to -- all the bases for  
23 my opinions, the treatises, statutes, regulations,  
24 published literature, are cited in my report.

25          Q. Okay.



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1           A. Except for some things that I have looked at,  
2 obviously, since -- since my report.

3           Q. All right. And that's really one of the things  
4 that I'm most interested in is your initial report was  
5 signed December 15th, 2015. There is a supplemental  
6 report after we disclosed the opinions of Dr. Miller.  
7 What have you looked at since you executed the  
8 supplemental report in terms of substantive material?  
9 Whether it's a deposition, article on the Internet,  
10 what, if anything, have you reviewed?

11          A. So some of the material -- obviously some of  
12 the material there I've reviewed subsequent; for  
13 example, the U.S. Pharmacist's articles --

14          Q. These two?

15          A. I didn't see -- I think there's one court case.

16          Q. United States of America versus Franck's Lab,  
17 Inc.; did you review those materials too?

18          A. Subsequent to the supplemental.

19          Q. Were you involved in the Franck's Lab, Inc.  
20 case?

21          A. No, not to my knowledge. No.

22          Q. What is the relevance to you of the order in  
23 the U.S. District Court for the Middle District of  
24 Florida in the Franck's Lab case?

25          A. Actually, it's a very good summary of the

1 history of the regulation of compounding.

2 Q. Okay. A summary that you agree with?

3 A. No, I didn't say that.

4 Q. No. It's a very good summary?

5 A. It's a -- it's a judge trying to -- let me not  
6 make any editorial comments whatsoever.

7 The reason I pulled it was I wanted to be  
8 familiar with judicial opinions on compounding, and that  
9 was one that I had not seen prior to my supplement.

10 Q. Okay.

11 A. Let me not make any editorial comments.

12 Q. All right. There's a group of materials,  
13 begins with a document that's to Tom Griscom from Tim  
14 Hyde, May 30th, 1995, that deals with some litigation in  
15 Florida and state issues. Apparently the focus of this  
16 is an op-ed by Dr. Miller. Is that why this group of  
17 materials is important?

18 A. This is a -- Tom C.Griscom was the chief  
19 lobbyist political operative for RJ Reynolds. I believe  
20 it's around the 1995 document, and Griscom is asking --  
21 is stating that he's having Dr. Miller write an op-ed  
22 criticizing FDA.

23 Q. Okay. And then there are two green binders  
24 with letters from Davis Wright Tremaine to Henry Miller,  
25 M.D., one dated July 25th, 2003, perhaps these are



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1       duplicates, on your behalf to Dr. Miller.

2           A. There's actually -- can I see -- they should be  
3       duplicates, but I'm happy to tell you what these are.

4           Q. Are these letters on your behalf from a law  
5       firm to Dr. Miller telling him to stop doing something?

6           A. Yeah. So there are two sets of letters here,  
7       and there's some attachments here. There is a June  
8       30th, 2003 letter from me to Dr. Miller saying that  
9       he -- that attaches a document from the Deputy  
10      Commissioner for Management and Systems that is a  
11      review, an audit, of my -- it says: Review and Audit of  
12      Dr. Kessler's Travel Vouchers and Imprest Fund  
13      Transactions During His Tenure.

14           Happy to read this letter into the record if  
15       you'd like.

16           Q. We'll just exhibit it.

17           A. But it basically says the -- informs, based on  
18       that document that I just cited, on that review, that  
19       Dr. Miller made false statements.

20           And then there is a subsequent letter from  
21       Davis Wright which cites false statements.

22           Q. Are those two green plastic binders duplicates?

23           A. Yes, sir. I believe so.

24           Q. All right.

25           A. We have to double-check. There's two --



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1 basically two letters, each with an attachment, both to  
2 Dr. Miller.

3 Q. Would you put them back in the green plastic?

4 A. I'd be happy to, sir.

5 Q. Then we've got, in one of these documents, an  
6 ASHP document dated 26 July 2012 that refers to MPA,  
7 methylprednisolone acetate --

8 A. As well as Depo-Medrol, if I'm correct, on the  
9 bottom of that.

10 Q. You're right. And it refers to shortages where  
11 Sandoz, Teva and Pfizer would not -- or could not  
12 provide a reason for the respective shortages?

13 A. That's what it states there.

14 Q. Yes.

15 A. You asked me a question about those companies,  
16 and that includes one of the statements. But which  
17 drug? Just so we're clear.

18 Q. Methylprednisolone acetate injection.

19 A. As opposed to Depo-Medrol, right?

20 Q. Well, no. They're all listed under the heading  
21 Methylprednisolone Acetate Injection.

22 A. Right.

23 Q. Then there's methylprednisolone acetate  
24 injection, Sandoz; methylprednisolone acetate injection,  
25 Teva --



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1           A. Right.

2           Q. -- and then Depo-Medrol injection, Pfizer, all  
3 under the same heading of Methylprednisolone Acetate  
4 Injection.

5           A. And then just for the record, so you can -- so  
6 we're complete, just read the whole document. These  
7 other headings.

8           Q. Available Products, there's a listing of those  
9 at the bottom of the page. And it goes on to the second  
10 page about Estimated Resupply Dates, Related Shortages,  
11 updating, disclaimers, and the fact that it's a  
12 publication by ASHP.

13           When we were talking previously, I think you  
14 told me that you looked at some FDA data on shortages;  
15 is that in this stack? I haven't seen it.

16           A. Which -- so I believe, if you just give me a  
17 second.

18           Q. If it's in your report I don't need you to find  
19 that again. But if there is something independent of  
20 your report you looked at, that's what I want to  
21 identify.

22           A. Yes. Let me just double-check so I can answer  
23 that.

24           So there's several hundred pages relating to  
25 shortage.



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1 Q. In the report?

2 A. And if you look at Schedule 3B, which goes on  
3 from page 254 to 324, that's all in the report. That's  
4 FDA's documents relating to shortages.

5 Q. Okay. And then the last two things in the  
6 stack include a definition under 21 U.S.C. 351 of when a  
7 drug or device is adulterated. Page and a line.

8 A. That's just 350 -- yeah, it's just the part of  
9 the statute that deals with old drugs as opposed to new  
10 drugs.

11 Q. Right.

12 And then finally, in the material you just gave  
13 me, we have two documents, FDA 428907, 428908, 428909,  
14 that reflect email communications between Bruce Ota, and  
15 Karen Archdeacon with respect to NECC.

16 A. That are part of the FDA FOI request that I  
17 received that was cited by Dr. Miller.

18 Q. What I'm going to do, Dr. Kessler, is I'm going  
19 to have my assistant here, Kaycee, put an exhibit number  
20 on each of these respective stacks while you and I  
21 continue to talk, and then we'll identify these as  
22 separate exhibits in just a moment.

23 A. Sure. And if I could just -- if any of your  
24 questions, I need those --

25 Q. Absolutely.

1           A. Thank you, sir.

2           MR. CHALOS: Mr. Gideon, for completeness,  
3 we've got an addendum to Appendix C here. I don't know  
4 if that's in the materials you've seen.

5           MR. GIDEON: It's not.

6           MR. CHALOS: I think it probably lists what  
7 you've seen. Let me hand you a copy of this.

8           MR. GIDEON: We'll mark the papers themselves  
9 so it's not separated from the folders.

10          This would have saved us a bunch of time.

11          MR. CHALOS: I believe Dr. Kessler mentioned  
12 this earlier today, but that's a copy of the index. The  
13 addendum to the index.

14          MR. GIDEON: Q. Does the witness have one  
15 of these in front of him?

16          A. Yes.

17          Q. On Appendix C, Dr. Kessler, in the first  
18 subcategory Document Type and Title, Articles and Texts,  
19 did you select the listed articles?

20          A. Again, we had a discussion on the word  
21 "select."

22          Q. Did you choose those or were they sent to you?

23          A. No. So you are asking about -- let's just take  
24 the first four for example purposes. So for example,  
25 on -- my recollection is on Vivian -- on both Vivian



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1 articles, I pulled those. Right? On the Beers, that's  
2 my book. The current shortages, it was a request of  
3 mine from counsel.

4 Q. Okay.

5 A. That's mine.

6 MR. GIDEON: All right. We'll make this --  
7 give me an exhibit sticker -- the very next one.

8 (Whereupon, Exhibits 1234 through 1240 were  
9 marked for identification.)

10 MR. GIDEON: I'm going to make Appendix C that  
11 we were just given Exhibit 1236 to this deposition. If  
12 this doesn't follow sequentially, we'll place something  
13 in its place.

14 Q. Have you read all of the materials listed in  
15 the bibliography to your report?

16 A. No. I wouldn't want -- well, I wouldn't want  
17 to -- the materials available to me, I wouldn't want to  
18 represent that I've read every single word of everything  
19 on that list.

20 Q. Well, let me just tell you, I'm a simple guy  
21 and I ask simple questions.

22 Have you read all the materials listed in the  
23 index?

24 A. I have not read -- I -- again, my answer is my  
25 answer. I have not read every line --

1 Q. Okay.

2 A. -- of all the materials.

3 Q. Your report reflects that you've looked at the  
4 Tennessee Healthcare Liability Act.

5 Do you recall that?

6 A. I believe I've referenced that in my report.

7 Q. The question is, have you read the Tennessee  
8 Healthcare Liability Act?

9 A. I'd have to go back and check. I don't  
10 remember it as of this moment in time.

11 Q. All right. You are licensed to practice  
12 medicine in the state of California?

13 A. I am.

14 Q. You have previously been licensed in other  
15 states during your career, have you not?

16 A. Yes. And those are sort of nonactive when one  
17 moves.

18 Q. Right. And I just want to confirm with you  
19 specific time frames in specific states.

20 You've previously been licensed in Connecticut,  
21 but it is now on inactive status, correct?

22 A. I believe that's correct.

23 Q. When were you licensed in Connecticut? From  
24 when until when?

25 A. Again --

1           Q. If the answer is "I don't recall," that's fine.

2           A. Well, I can generally tell you when we moved to  
3 Connecticut in 1997 I applied for licensure. And again,  
4 I don't quite know what inactive status means, whether  
5 that's -- whether I'm still licensed. I've not asked  
6 for the license to be active, I think I just notify  
7 them. But I'm not paying active -- I'm not paying  
8 active dues. Only --

9           Q. You don't consider yourself to be licensed to  
10 practice medicine in Connecticut?

11          A. Again, I'm on -- we could talk to the board. I  
12 was licensed, I asked to be put on nonactive status. I  
13 don't -- you know, I'm not paying dues there at the  
14 present time.

15          Q. When were you licensed to practice medicine in  
16 Maryland?

17          A. When we moved to -- well, I think it was  
18 probably two periods of time. I did my residency at  
19 Hopkins.

20          Q. What was the time frame?

21          A. So my residency, late '70s to early '80s. And  
22 then I'm sure I -- I have to refresh my recollection --  
23 but I think when I moved to FDA, I probably moved my  
24 license from -- not moved, but I probably applied for  
25 Maryland licensure.



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1 Q. You were licensed as a resident in pediatrics?

2 A. That's a little complicated, as you know.

3 Residents are under a general statute. I don't think --  
4 I'd have to go back and check to see whether I held a  
5 particular license or whether Hopkins held the license.

6 Q. Have you ever been licensed to practice  
7 medicine in New York?

8 A. Yes.

9 Q. From when to when?

10 A. When I was medical director of Einstein  
11 Hospital, so in the 1980's.

12 Q. When to when?

13 A. When I finished my residency, what, about '82,  
14 probably. Again, I'm on inactive status so I don't want  
15 to give you an end date. But I don't pay dues in  
16 New York.

17 Q. So from the time frame since when have you been  
18 licensed to practice medicine in California and  
19 California alone?

20 A. So I don't know the term "California alone"  
21 because we have these inactive statuses, and I'll let  
22 others do that.

23 But I can probably pull my license if you want,  
24 now, from my wallet. I am sure -- I mean, I believe  
25 I've been licensed from 2003 to the present.



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1 Q. You have never been licensed to practice  
2 medicine in the state of Tennessee?

3 A. I have not.

4 Q. And you've never been licensed to practice  
5 medicine in any of the states that surround Tennessee,  
6 correct?

7 A. That's correct, sir.

8 Q. Have you ever operated, yourself, an ambulatory  
9 surgery center that was licensed in Tennessee or any of  
10 the states that surround Tennessee?

11 A. Not in Tennessee or the states surrounding  
12 Tennessee, no.

13 Q. Have you ever operated an ASC in any state?

14 A. I'd have to go back and check licensure,  
15 whatever, on -- I'd have to go back and think about that  
16 question in the various capacities of whether I had  
17 responsibility at Yale, New York, or here in the various  
18 capacities.

19 There certainly were ambulatory surgical units  
20 in all three. I'm not sure -- I'd have to go back and  
21 check who held the licensure, the institution, and what  
22 my role was.

23 Q. Have you ever been licensed as a pharmacist?

24 A. No, I've not been licensed as a pharmacist.

25 I've chaired pharmacy and therapeutics committees as a

1 medical director, but I've never been licensed as a  
2 pharmacist.

3 Q. Okay. Have you ever offered testimony claiming  
4 to be an expert in the practice of medicine where the  
5 defendant in the case was another physician?

6 A. Where the defendant was a physician. I would  
7 have to go back and review. Nothing -- I just have  
8 to -- I don't know the answer to that question. I'd  
9 have to go review the cases that I've testified in.

10 Q. Well, we're going to get to your listing that  
11 was attached to the disclosure in this case of your  
12 litigation-related involvements over the last several  
13 years, but do you recall ever being somebody who was  
14 offered by a lawyer as an expert on standards of care  
15 for a pediatrician? Use that as the first example.

16 A. I'd have to go back and review -- review my  
17 testimony.

18 Q. In how many different cases?

19 A. Well, for example, I mean, I just have to --  
20 let me tell you what was going through my head and  
21 just -- maybe you can -- so again, if you look, for  
22 example, in a case Allergan and Botox, and I'd have to,  
23 for example, look who the defendants were.

24 And I am sure that questions were asked of me  
25 about the appropriate use of medicine by doctors in a

1       certain -- I mean, for example, in that matter. We'd  
2       have to go back and look exactly who the defendants are.  
3       Obviously there was a pharmaceutical company. There was  
4       also a defendant, but I don't know if the individual  
5       doctors -- I think the individual doctor were probably  
6       also parties, but I don't want to represent that without  
7       checking.

8           Q. Well --

9           A. Then the question, for example, is it  
10      appropriate to use a drug off label, and what that  
11      standard of care is. So I've testified with regard to  
12      those types of issues, certainly.

13          Q. Well, I want an answer to my question. I'm not  
14      asking you about what comments you may have made in a  
15      case about certain issues. I want you to tell me, do  
16      you recall ever being disclosed as an expert where the  
17      defendant was not Allergan or Bard or McNeil, but an  
18      individual physician?

19          A. So I've answered that question.

20          Q. And the answer is what, you don't recall it?

21          A. I've answered the question. No, the answer is  
22      we would have to go check to see all the defendants in  
23      those cases.

24           I do remember, with regard to individual  
25      conduct -- again, I have to check who the defendants

1       are -- opining what was appropriate for individual  
2       doctors to do.

3           Q. Uh-huh.

4           A. So I have testified on that in a number of  
5       instances.

6           Q. Okay. Now, you told me a few moments ago, as  
7       you discussed your background, that you did your  
8       residency at Hopkins; was it in the pediatrics program?

9           A. Yes.

10          Q. And you completed the three-year pediatrics  
11       residency at Hopkins?

12          A. I did.

13          Q. Are you board certified in pediatrics?

14          A. So I was for 30 years. I took my initial  
15       boards, I took my recertification boards several times,  
16       and I'm a professor of pediatrics; I've just chosen not  
17       to take the recertification boards. I may at some  
18       point. So at the moment I'm not board certified in  
19       pediatrics, but I have been for some 30 years, and I'm a  
20       professor of pediatrics.

21          Q. Your residency training in pediatrics was from  
22       1979 to 1982 at Hopkins, correct?

23          A. Yes, sir.

24          Q. You are not board certified in the field in  
25       which you obtained your residency training as you and I

1 speak today, are you?

2 A. I'm not board certified, I'm board eligible. I  
3 was board certified and I just chose not to sit for the  
4 recertification.

5 Q. So your board certification in pediatrics  
6 expired?

7 A. Several years ago when I decided not to just  
8 sit for recertification.

9 Q. And when was that?

10 A. I'd have to go -- it was a few years ago.

11 Q. Did the American Board of Pediatrics have a  
12 program called maintenance of certification?

13 A. Yes.

14 Q. Did you drop out of the maintenance of  
15 certification process several years in advance of the  
16 actual expiration date of your board certification?

17 A. You know, I'd have to check exactly what that  
18 was, but I basically dropped out.

19 Q. Yeah.

20 A. But we'd have to find that exact. I don't  
21 remember exactly the dates you are talking about.

22 Q. As you're probably familiar, a number of  
23 hospitals will condition the ability to obtain staff  
24 privileges at an institution upon a number of factors,  
25 and one of which is frequently the physician's board



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1 certification by one of the authorized ABMS board  
2 certifying entities; you are quite familiar with that?  
3 A. I've chaired medical staff committees.  
4 Q. Sure.  
5 A. So I know that exactly.  
6 Q. All right. Do you have staff privileges to  
7 admit a patient to any hospital in greater  
8 San Francisco?  
9 A. I -- not at the moment. For 30 -- for my  
10 entire career, medical director at Yale, here, I did.  
11 But again, I gave that up the last several years. I'm  
12 licensed to practice medicine.  
13 Q. We've covered that.  
14 A. I'm licensed to practice medicine, but I gave  
15 that up. I gave up my privileges voluntarily just  
16 because I, you know, spend most of my time doing  
17 research, et cetera.  
18 Q. How long has it been since you last had the  
19 opportunity to admit a patient to any hospital where you  
20 have had privileges in the past?  
21 A. Last several years. I forget exactly when it  
22 was.  
23 Q. What's your best estimate of what year it was  
24 that you surrendered your status of having admitting  
25 privileges?

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1           A. I voluntarily didn't reapply.

2           Q. When would that have been?

3           A. I don't have the exact date.

4           Q. And where did you not reapply?

5           A. To the UCSF Medical Center, I had privileges  
6 here. I was a hospitalist. And then I just -- I  
7 decided to give that up.

8           Q. Okay. Did -- as you well know, it's common  
9 with university teaching centers that frequently they  
10 will have a flagship hospital, but they'll oftentimes  
11 have relationships with hospitals in the community so  
12 they can give their residents more of a varied  
13 experience. Do you know what I'm talking about?

14           A. Yes.

15           Q. All right. Did you have staff privileges  
16 anywhere other than UCSF?

17           A. I'd have to double-check. I'm pretty sure I  
18 had staff privileges at San Francisco General, certainly  
19 giving grand rounds there, et cetera. But I believe all  
20 my active hospitalist duties were at UCSF.

21           Q. Okay.

22           A. I've lectured at the other places, I've taught  
23 at the other places, but I think I've only actually seen  
24 patients at UCSF.

25           Q. Can you tell me the last year you actually



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1 recall admitting a patient to the hospital as the  
2 attending physician?

3 A. I'd have to go back and check. It was during  
4 my hospitalist -- when I was a hospitalist. And even  
5 then, I probably didn't admit -- the residents probably  
6 admitted and admitted under my name.

7 Q. Right.

8 A. But, I mean, certainly in the 2000s --  
9 somewhere -- I don't know the exact date.

10 Q. When did your tour as a hospitalist come to an  
11 end?

12 A. I don't know. I probably stopped being a  
13 hospitalist 2007 or so. 2008. But that's just an  
14 approximation.

15 Q. And as a hospitalist, were you paid a thousand  
16 dollars an hour for your services?

17 A. So I didn't -- I was paid by the State of  
18 California. We didn't bill by the hour.

19 Q. Well, did your compensation for working as a  
20 hospitalist come close to the thousand-dollar-an-hour  
21 charge for the time talking to me today?

22 A. My salary was a matter of public record. We  
23 can go back and look and you can calculate hours and  
24 what that comes to.

25 Q. Do you know what the comparison was?

1           A. I probably -- I don't know. My guess, it was  
2 approximately -- probably about a half a million dollars  
3 a year. Don't hold me to what my salary -- maybe it was  
4 600, 700. I don't remember, sir.

5           Q. And as a hospitalist, did you work 50, 60 hours  
6 a week, 50 weeks a year?

7           A. I work all the time. I don't know -- when you  
8 are a hospitalist, I think I was on call all the time,  
9 every day, for -- but I -- but if you look -- I was only  
10 a hospitalist for several weeks a year. So maybe it was  
11 two weeks.

12          Q. Okay.

13          A. So I mean, so I think you would probably say I  
14 did that pro bono as a hospitalist. There was no  
15 obligation for me to do that, so I think I probably did  
16 that pro bono.

17          Q. So you stopped working as a pediatric, I  
18 assume, hospitalist in 2007, correct?

19          A. I said I wasn't sure about the date, I gave  
20 that as an approximate date.

21          Q. But your services were as a pediatric  
22 hospitalist, correct?

23          A. Yes, I was a pediatric and adolescent -- child  
24 and adolescent.

25          Q. Now, up to and including the time when you did

1       not reapply for staff privileges, had you ever performed  
2       an epidural steroid injection on anyone?

3           A. I don't believe so.

4           Q. Have you ever performed any form of invasive  
5       delivery of steroids into the spinal column during your  
6       career?

7           A. I don't believe -- I've certainly entered the  
8       spinal column, but I never believe that I pushed  
9       steroids.

10          Q. Well, I would find it absolutely unbelievable  
11       that a pediatrician somewhere along their career hasn't  
12       done spinal taps --

13          A. That's what I just said.

14          Q. -- both emergency and afterwards.

15           But other than drawing off CSF for the purposes  
16       of diagnosis or diminishing pressure, have you ever  
17       delivered drugs into the epidural space anywhere in the  
18       spinal column?

19          A. So I've certainly administered methotrexate and  
20       other things intrathecally.

21          Q. Other than that?

22          A. I'd have to go back and check.

23          Q. The methotrexate delivery intrathecally in a  
24       child would be for what?

25          A. Chemotherapy.

1           Q. Did you have a fellowship program in pediatric  
2 oncology?

3           A. Was I trained?

4           Q. It's designed to be a simple question.

5           Did you have a formal fellowship program in  
6 pediatric oncology?

7           A. So I certainly have those programs. I mean, in  
8 my medical center those programs exist. I didn't do  
9 those programs. I pushed intrathecal methotrexate  
10 certainly as a resident.

11          Q. Okay. All right. Now --

12          A. I was accepted into a fellowship program in  
13 pediatric oncology but I decided not to go.

14          Q. All right.

15          A. I became medical director of the hospital.

16          Q. At Einstein?

17          A. I did.

18          Q. Okay. Now, other than pediatrics, have you  
19 been board certified in any other field at any time?

20          A. No.

21          Q. Have you ever sought board certification in any  
22 other field at any time?

23          A. No, I did not.

24          Q. Have you ever been board eligible in any other  
25 field at any time?



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1           A. You know, I don't believe so. Maybe preventive  
2 medicine, other things -- I'm a professor of  
3 epidemiology, biostatistics. I don't know what that  
4 grants me. We'd have to look.

5           Q. Up to and including, if your estimate is  
6 correct, 2007, you came to -- you came to UCSF 2003,  
7 didn't you?

8           A. I did.

9           Q. Okay. From 2003 until 2007, did you actually  
10 have staff privileges at an outpatient diagnostic  
11 center?

12          A. We'd have to check the bylaws. As you know,  
13 UCSF has many different clinics associated, and I just  
14 don't want to use -- I'm pretty sure my privileges would  
15 have attached using the specific word outpatient  
16 diagnostic center. Certainly there were outpatient  
17 clinics and outpatient ambulatory units, and I'm sure my  
18 privileges attached to those.

19          Q. Well, when I use the term outpatient diagnostic  
20 center I'm being more specific than that. The term I --  
21 the meaning I intend to convey with that is an ODC,  
22 similar to what's licensed in Tennessee, that will have  
23 the capacity to do a CT myelogram, MRI, will have the  
24 capacity to infuse Omnipaque for the purposes of  
25 diagnostic studies, in some cases they'll do



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1 bronchoscopies.

2 A. Sure.

3 Q. Did you ever have staff privileges at an  
4 outpatient diagnostic center as I have described?

5 A. So I believe UCSF, my staff privileges  
6 accounted -- encumbered all the UCSF clinics. Have to  
7 go back and look at the bylaws.

8 Q. Okay.

9 A. And certainly those clinics included those --  
10 had those kind of services available.

11 Q. When you came to UCSF, were you given tenure  
12 from the beginning?

13 A. Yes.

14 Q. And tenure at UCSF means what?

15 A. How long do you want it to mean?

16 Q. Good response.

17 Does tenure mean that you get to hold the  
18 faculty position for life if you are tenured?

19 A. I let others judge what tenure is.

20 Q. Okay. Now, your CV represents to me that you  
21 were the dean of the UCSF School of Medicine from 2003  
22 to 2007, correct?

23 A. That's correct.

24 Q. You were fired on December 13th, 2007 as the  
25 dean of the UCSF school of medicine?



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1           A. As a dean, but not as the professor of  
2 pediatrics.

3           Q. And your termination as dean of the UCSF School  
4 of Medicine was upheld by a hearing committee at UCSF on  
5 January 11th, 2010, correct?

6           A. So, again, I was a whistleblower in a matter,  
7 and I will leave it to others to decide what is  
8 confidential.

9           Q. Was your termination of December 13th, 2007  
10 upheld by a hearing committee on January 11th, 2010?

11          A. I don't believe -- I believe that there are  
12 certain things that are confidential. I don't believe  
13 that that was a matter of public record, but I don't  
14 know.

15          Q. Let's have exhibits -- items 2 and 3.

16           I'm handing you Exhibit 1245, Dr. Kessler.

17          MR. CHALOS: What happened to the other  
18 exhibits?

19          MR. GIDEON: She's stacking them up.

20          MR. CHALOS: I'm sorry, you marked the --

21          MS. WEETER: I marked all those.

22           (Whereupon, Exhibits 1241 through 1245 were  
23 marked for identification.)

24          MR. GIDEON: And we'll cover those sometime in  
25 the future.

1           Q. Exhibit 1245 is a complaint you filed acting as  
2 lawyer for yourself in the United States District Court  
3 for the Northern District of California in the  
4 San Francisco Division.

5           If you look at page 18 of the complaint, you'll  
6 see your signature, correct?

7           A. I see my signature there. I believe the  
8 Government Accountability Project represented this.

9           Q. Well, I see only a David Kessler signing the  
10 complaint pro se in the complaint filed December 12,  
11 2008.

12           Do you see a signature by any other lawyer?

13           A. No, but as I understand this, I mean, I was  
14 represented by the Government Accountability Project.

15           Q. Okay. Well, subsequently a summary judgment  
16 was granted in favor of the people you sued; isn't that  
17 correct?

18           A. This is with regard to retaliation complaints.

19           Q. Well, with respect to the entire complaint.

20           A. But if you read your question, your question  
21 was whether my firing was upheld. This is whether there  
22 was retaliation.

23           Q. Well --

24           A. Under the civil rights law.

25

(Whereupon, Exhibit 1246 was marked for identification.)

MR. GIDEON: Q. I'm handing you Exhibit 1246, which is the Order Granting Defendants' Motion for Summary Judgment: Requiring Plaintiff's Opposition Papers to be Filed in an order entered October 5th, 2011 by Phyllis J. Hamilton, United States District Judge.

This dismissed your complaint, did it not?

A. There was a -- if you read the last opinion of her -- the last paragraph, there was -- what she dismissed, not on the merits, but she dismissed my grievance, which was a retaliation grievance.

Q. Okay.

A. Under the whistleblower, again, the Civil Rights Act.

Q. If you'll look at page 8 of that summary judgment order that's in front of you?

A. Yes.

Q. Focus right there on page 8, you will see the finding by the United States district judge that on January 11th, 2010 --

A. Show me which sentence you are at.

Q. It's the first full paragraph on page 8 of the opinion. Page 8 of 25.



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1           A. Right.

2           Q. It states, quote: On January 11, 2010, the  
3         Hearing Committee issued its finding of fact,  
4         conclusions and recommendations.

5                   And then there's a citation to certain  
6         documents.

7           A. Yes.

8           Q. And then it says: The Hearing Committee  
9         unanimously concluded that Dr. Kessler's Grievance  
10       should be denied in its entirety.

11          A. The whistleblower -- the retaliation grievance.  
12       I was labeled as a whistleblower. That was agreed to,  
13       and they denied retaliation.

14          Q. Then it says: The Hearing Committee found that  
15       "the reason for Dr. Bishop's decision, in consultation  
16       with his superiors, to terminate Dr. Kessler from his  
17       Deanship was not retaliation for Dr. Kessler having made  
18       protected disclosures. Rather, Dr. Bishop's decision  
19       reflected his view that Dr. Kessler could no longer  
20       effectively lead the School of Medicine."

21                   I've read that correctly, have I not?

22          A. You have.

23          Q. All right. Wasn't this summary judgment order  
24       the termination of the litigation between you and the  
25       University of California at SF?

1           A. This is exactly what this represents.

2           Q. It is what it is, hah?

3           A. It is what it is.

4           Q. Okay. Have you had any subsequent litigation  
5 with UCSF over your relationship with that institution?

6           A. Again, we'd have to check with the Government  
7 Accountability Project, but I don't believe so.

8           Q. Have you had any other personal litigation  
9 against lawyers, doctors, or corporate entities?

10          A. No.

11          Q. Have you had any other personal litigation --

12          A. Excuse me. At what point in time?

13          Q. Any time.

14           We found this on Pacer, which you know is the  
15 federal court system. Have you had any other litigation  
16 against another medical school --

17          A. No.

18          Q. -- during your career?

19          A. No.

20          Q. Have you had any litigation against a company  
21 or an individual over another dispute during your  
22 career?

23          A. During my career in my professional capacity?

24          Q. Yes.

25          A. No.



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1 Q. Have you had any litigation with any law firms  
2 over your testimony or your fees?

3 A. No.

4 Q. Okay. I mentioned earlier, when we first  
5 started talking, that the FDA website reflects that you  
6 were the commissioner of the Food, Drug and Cosmetics  
7 Agency from November 8th, 19 --

8 A. Food and Drug Administration.

9 Q. Okay. Food and Drug Administration.

10 A. Please.

11 Q. I'll get it.

12 A. Thank you.

13 Q. The website reflects your tour of duty was  
14 November 8th, 1990 to February 28th, 1997. Does that  
15 sound correct?

16 A. Again, that sounds correct. That was  
17 probably -- we have to check when I became -- officially  
18 it was confirmed. I probably didn't start until  
19 December, I think I mentioned to you.

20 Q. You did.

21 When did you actually become employed by Yale  
22 University?

23 A. Probably July 1st, 2000 -- I'm guessing July  
24 1st, 1997.

25 Q. When you left the FDA, did you already have, in

1 hand, an offer to join Yale?

2 A. No, I did not. I deliberately didn't -- I had  
3 no contact with Yale prior to FDA.

4 Q. Do you remember my request at the beginning  
5 that I ask succinct questions and you give me a succinct  
6 answer? I'd like to ask it again.

7 When you left the FDA, did you have a job offer  
8 in hand from Yale University?

9 MR. ARBITBLIT: Objection. Asked and answered,  
10 Counsel.

11 THE WITNESS: If my answer was -- is direct as  
12 I could be, was no, I did not.

13 MR. GIDEON: Good.

14 THE WITNESS: I mean, it's on the record.

15 MR. GIDEON: Q. Okay. How long did it  
16 take you before you found employment after leaving  
17 the FDA February 28th, 1997?

18 A. I think in a matter of days. I think that  
19 weekend, if I'm right. I don't remember exactly which  
20 weekend it was, I recall coming home from the  
21 dry-cleaner and my wife saying Rick Levin called and he  
22 asked whether you want to be dean of Yale Medical  
23 School.

24 Q. Was Rick Levin the chairman or chancellor of  
25 Yale University?

1           A. He was the president. So I think it was a  
2 matter of very soon thereafter. That call from Rick was  
3 unsolicited.

4           Q. Okay. You handed us, and we're going to  
5 exhibit them in a few moments, two green binders that  
6 reflected correspondence from a lawyer on your behalf to  
7 Dr. Miller.

8           A. And --

9           Q. And --

10          A. And a letter from me to Dr. Miller.

11          Q. Fine. I haven't had a chance to look at them.  
12 I haven't had a chance to read the pages, so I don't  
13 know the content.

14          A. Uh-huh.

15          Q. But you did mention, when you were describing  
16 them, there was some kind of either formal or informal  
17 audit document attached to one of the letters.

18          Do you recall that?

19          A. Yes.

20          Q. Okay. Was there an evaluation audit or  
21 examination of your billing the FDA for travel-related  
22 expenses at the time you left on February 28th, 1997?

23          A. Can I have those documents?

24          Q. Sure.

25          A. So as I -- as I remember --



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1           Q. Hold on just a second so I can hand you the  
2 documents.

3           A. Thanks.

4           Q. I'm going to hand Dr. Kessler two documents  
5 right now. One is entitled Exhibit 1240 that begins  
6 with a letter of July 25th, 2003 to Dr. Henry Miller.  
7 That's the first page.

8           Then there is a second exhibit, 1239, that has  
9 the same letter in this folder.

10          And here are those two back.

11          A. Thank you, sir.

12          Q. And the pending question, Dr. Kessler, is  
13 whether when you left the FDA, was there an audit  
14 underway to determine if you had appropriately accounted  
15 for travel expenses?

16          A. No, I don't think that -- I don't think -- as  
17 you phrased the question, the answer would probably be  
18 no. But let's look at this letter because this probably  
19 has the information.

20          Q. In exhibit which number?

21          A. Well, there is -- if you take Exhibit 1237  
22 (verbatim), and if you look at this January 24th, 1997.

23           So let me give you a little more context for  
24 your -- to the answer to that, best I can do this.

25           So there is -- there was first a -- we can make



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1       this very simple.

2           Q. Good.

3           A. I was not involved with -- as this finding  
4 shows, I was not involved at all with my travel  
5 vouchers. I didn't -- as this says, I did not  
6 personally handle my travel vouchers or imprest fund  
7 transactions. I provided receipts or -- when it was  
8 requested, but I wasn't involved in the details  
9 reviewing and signing vouchers or transactions.

10           But I was -- but so -- but I did -- I  
11 requested, in 1993, if you look, late 1993 or 1994, just  
12 as a matter of prudence, the Office of Financial  
13 Management reviewed his vouchers to assure compliance  
14 with regulations, and a review found them to be in  
15 order.

16           So the first time I just -- I voluntarily -- I  
17 just said please, just review all my travel, and they  
18 did. And then I think what the history was -- and  
19 again, you have to trace this. But there was some -- I  
20 think it's in my book. There was some 650 FOI requests  
21 on me. And you can trace it through an outside  
22 third-party group that requested just, again, hundreds  
23 of requests for documents.

24           That, if you look, I think you can -- if you  
25 connect the dots, that was -- we were involved in --



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1 it's about investigation of the tobacco industry and  
2 there were connections to that group with the tobacco  
3 industry.

4 I don't know the full -- I've never been privy  
5 to the full handoff of that group as a result of the  
6 tobacco industry engaging with that group and monitoring  
7 things and then handing it off.

8 But then it says in February of 1996, a  
9 congressional inquiry into my travel eventually spurred  
10 interest in the Associated Press. The congressional  
11 inquiry was limited. I asked the scope be expanded to a  
12 complete audit of his travel documents. The  
13 commissioner asked that the audit be conducted at a  
14 level of detail beyond which was normally devoted, and  
15 then steps were taken.

16 And then the audit of the six years travel  
17 vouchers and imprest funds from 1991 to 1996 -- so this  
18 was done before I left -- reveal 275 taxi claims with a  
19 total reimbursement of \$8,000. And then it talks about  
20 an over-reimbursement of 823. But that was done at the  
21 time.

22 Bottom line, though, is this demonstrates I was  
23 not -- I had nothing to do with my travel expense forms  
24 whatsoever.

25 Q. I didn't ask you to admit complicity. I just

1       wondered if there was an audit underway when you left.

2           A. So the answer is no. It looks like the audit  
3       was complete.

4           Q. Okay.

5           A. And there was several audits done, some at my  
6       request, as this lays out.

7           Q. You graduated from law school in what year?  
8       Not that long ago. At least for me it's not that long  
9       ago.

10          A. So I probably -- I graduated, what, I did two  
11       years at University of Chicago and a third year at  
12       Harvard. So Harvard was '78.

13          Q. Okay. Have you ever been licensed to practice  
14       law in any state?

15          A. Never sat for a bar. Chose not to take a bar.

16          Q. So the answer is what?

17          A. Never took a bar.

18          Q. So never licensed to practice law anywhere in  
19       the United States?

20          A. Because I never took a bar, yes. I graduate --  
21       have my law degree.

22          Q. You've never taken a deposition, argued a  
23       motion in court under the authority of another lawyer,  
24       have you?

25          A. No, but I've taught law school.

1 Q. Without being licensed?

2 A. I don't think -- I've taught law school at  
3 Columbia Law School. I've taught food and drug law.  
4 You don't need to be licensed to be a professor, to have  
5 an academic appointment.

6 Q. True.

7 A. Thank you.

8 Q. You became familiar with the definition of  
9 cause in fact in one or both of the law schools you went  
10 to, didn't you?

11 A. Cause in --

12 Q. Did you have a torts class when you were in law  
13 school?

14 A. Richard Epstein taught me torts.

15 Q. So the answer is yes?

16 A. That answer is probably -- well, if we were  
17 joking, I would probably say no, if you know Richard.

18 Q. Did you have a torts class, irrespective of the  
19 quality of the instructor, when you were in law school?

20 A. Richard's interest was not really torts, as you  
21 know that. It was law and economics. So yes, I did  
22 take torts.

23 Q. Did you become familiar with the not  
24 complicated concept of cause in fact when you were in  
25 law school?



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1                   MR. CHALOS: Objection to the form.

2                   THE WITNESS: I probably saw it -- the issues  
3 of causation is what I would do, is probably what I was,  
4 you know, generally familiar with causation issues.

5                   MR. GIDEON: Q. Were you introduced to the  
6 uniform commercial code when you were in law school?

7                   A. I certainly took courses in --

8                   Q. UCC?

9                   A. -- yes, sir.

10                  Q. You --

11                  A. I leave it -- on that there are very few things  
12 I would say -- you know, on that one, please talk to  
13 others on the UCC.

14                  Q. You don't claim any expertise under the UCC, do  
15 you?

16                  A. I took Andy Kaufman's UCC class, but I would  
17 strongly urge you to consult somebody else.

18                  Q. I'll ask the question again. Irrespective of  
19 who your instructors were or were not, you don't claim  
20 to be an expert in the application of the UCC?

21                  A. I thought a court determined that. I probably  
22 have a greater knowledge than the average citizen, but I  
23 certainly don't want to get involved in UCC issues.

24                  Q. Okay. Tell me when Saint Thomas Outpatient  
25 Neurosurgical Center first began purchasing product from



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1 medical sales management and NECC. Month and year.

2 A. I'd have to look it up. I don't want to guess.  
3 I think it was probably around 2011, but I have --  
4 there's evidence in that documentation, I believe.

5 Q. Did you look at the exhibits to Debbie  
6 Schamberg's deposition as you formed your opinions in  
7 this case?

8 A. Yes. I mean, I certainly --

9 Q. Let me have No. 4.

10 A. As I read that deposition.

11 MR. ARBITBLIT: Counsel, if you are switching  
12 topics, we've been going for about an hour and 25  
13 minutes.

14 MR. GIDEON: Whenever you want to stop.

15 MR. ARBITBLIT: Dr. Kessler, if you want to  
16 take a break --

17 THE WITNESS: If you are in the middle of a  
18 series of questions, why don't we go through. I'm  
19 perfectly happy to.

20 MR. GIDEON: It's at your pleasure. I don't  
21 care. If you want to take a break -- Don, if you want  
22 to take a break, it's fine. I will continue all day  
23 long without stopping, I will warn you about that.

24 MR. ARBITBLIT: I know the feeling.

25 MR. GIDEON: So may I have -- we can discuss



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1       this and then we'll take a break after that, how does  
2       that sound?

3                    MR. ARBITBLIT: Fine.

4                    (Whereupon, Exhibit 1247 was marked for  
5                    identification.)

6                    MR. GIDEON: Q. I'm going to hand you what  
7       was marked as Exhibit 31 to the Schamberg  
8       deposition, but it's Exhibit 1247 to yours.

9                    And we've arranged this, Dr. Kessler -- first  
10          you can take a look at it and see if you don't have some  
11          working recollection of seeing these materials. I think  
12          your answer will be yes, but tell me independently  
13          whether that is your answer.

14          A. I think I -- not only is it yes, but I believe  
15          I cite this in my report or in my supplemental.

16          Q. Which is why I asked you earlier about the  
17          materials that you selected versus the ones that you  
18          focused on, in part to determine your familiarity with  
19          the materials.

20                   But you do recall seeing the documents in the  
21          exhibit that's in front of you, don't you?

22          A. I take -- I mean, I take you at your  
23          representation that this is the whole document. I  
24          haven't turned every page, but I certainly see certain  
25          things that I've seen before.



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1           Q. And you can see, in the very first document in  
2 this exhibit, it's an email from Jason Salvucci,  
3 September 27th, 2010, to Debbie Schamberg?

4           A. Yes.

5           Q. Where he refers to meeting her in Franklin at  
6 the show?

7           A. Yes.

8           Q. Now, what experience have you had with the  
9 Federation of Ambulatory Surgery Centers? FASCA?

10          A. Probably none.

11          Q. Have you ever attended a FASCA show?

12          A. Probably not. I have no recollection.

13          Q. What limitations were placed by FASCA on who  
14 could be an exhibitor at their shows?

15          A. You'd have to ask FASCA.

16          Q. It's okay to just say I don't know.

17          A. You would have to ask FASCA.

18          Q. You don't know, do you? You don't know?

19          A. I could find -- if there's a document, I'm  
20 happy to look at the document. But I don't know.

21          Q. Did the Food and Drug Administration appear at  
22 FASCA shows?

23          A. We'd have to go and look at the record. I  
24 don't know the answer to that.

25          Q. In order for someone from FDA to go to a show



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1 as an exhibitor, would they have to get some advance  
2 authorization?

3 A. To show up as a -- to go to a technical --

4 Q. Not to go -- to go as an exhibitor to a FASCA  
5 show --

6 A. If FDA wanted to exhibit?

7 Q. Yes.

8 A. If FDA wanted to exhibit, they would apply as  
9 any other exhibitor is my guess.

10 Q. But within FDA, let's say I was someone who  
11 worked for FDA during the time you were there and I  
12 wanted to attend, for whatever reason, a FASCA show as  
13 an exhibitor, would I have to get permission to do so?

14 A. Well, you probably have to fill out certain --  
15 certainly attendant permissions. You would probably  
16 have to fill out a travel voucher if you wanted to go  
17 to -- in anticipation if I'm going to fly there.

18 If I was going to drive there, and it was local  
19 and it was in my jurisdiction, I -- I can make the  
20 decision whether it was in my jurisdiction and I had a  
21 reason to go for FDA business, I could probably make  
22 that decision.

23 Q. Do you know if FDA acted as an exhibitor at  
24 ambulatory surgery center shows, FASCA shows, where FDA  
25 had a booth and they were in the same sequence as the

1       booths for NECC and Ameridose? Do you know whether  
2       that's true or not?

3           A. I'd have to check. I don't know.

4           Q. Okay. You will see, it's item No. 3, in the  
5       exhibit ahead of you, is methylprednisolone acetate.

6           A. Yes. You are on page 3, is that what you said?

7           Q. Yes, sir. The third page in the exhibit should  
8       say methylprednisolone acetate.

9           A. Yes.

10          Q. As of the date that these materials were sent  
11       to Debbie Schamberg, September 27, 2010, was there a  
12       commercially available preservative-free  
13       methylprednisolone acetate?

14          A. I'm not aware of that, but depends -- I'm not  
15       aware of one.

16          Q. Okay.

17          A. I'm aware of the -- Pfizer's product that -- of  
18       Depo-Medrol. I think Ms. Schamberg says that that was  
19       preservative-free, but everything I know, that contains  
20       benzyl alcohol. So to me that would be a preservative.

21          Q. Did the Depo-Medrol, the branded product from  
22       Pfizer, also include an active ingredient called  
23       picolinium?

24          A. I think you would have to give me the label to  
25       refresh --

1 Q. We would just read the label together --

2 A. Yes.

3 Q. -- and see if picolinium is present or not?

4 A. If picolinium is on the label, then it was in  
5 the product.

6 Q. Is picolinium a preservative?

7 A. I'd want to check.

8 Q. Okay.

9 A. I thought -- I'd want to check. When I looked  
10 at the -- the Depo-Medrol, the one warning about  
11 preservative was benzyl alcohol. But we can -- why  
12 don't you just give me the label and I can answer it.

13 Q. Your report refers to Depo-Medrol being  
14 approved in 1959 originally by the FDA. And the formula  
15 for Depo-Medrol has continued to include benzyl alcohol  
16 for approval up to and including the present date,  
17 doesn't it?

18 A. I believe at .99 percent or something like  
19 that.

20 Q. Yes.

21 A. If you can do me a favor and just hand me the  
22 label for Depo-Medrol, I think you could -- I'd want to  
23 testify based on the label.

24 Q. We will get the label for you.

25 A. Great. I appreciate that.



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1 Q. We'll continue with these documents before we  
2 take a break.

3 You see the representation on page 3 by NECC  
4 that all CSP formulations are USP 797 compliant. Do you  
5 consider yourself to have working familiarity with  
6 USP 797?

7 A. I think I was. USP and FDA -- I'm sorry,  
8 working familiarity?

9 Q. Yes.

10 A. I'd have to -- I'm certainly working  
11 familiarity with USP. I was on the board as  
12 commissioner of USP. But I don't have working  
13 familiarity with that statute on the basis of my --  
14 sitting here today.

15 But if you give me the pharmacopeia standards,  
16 I'm happy to discuss those.

17 Q. Prompted by having a copy of USP 797 in front  
18 of you, you feel comfortable discussing the language but  
19 you don't have it memorized; is that what you are  
20 telling me?

21 A. I'd be happy to discuss it --

22 MR. CHALOS: Hang on a second. Object to the  
23 form.

24 THE WITNESS: Again, I think exactly -- if you  
25 hand me the standards, I'll tell you. Certain standards

1 I feel more comfortable than others --

2 MR. GIDEON: Q. Right.

3 A. -- discussing. Because -- so just hand me the  
4 standards and I'd be happy to tell you which ones I'm  
5 comfortable doing.

6 Q. Okay. Now, where is there any statement on  
7 page 3 of the document that I handed to you, that  
8 exhibit that has methylprednisolone acetate at the top,  
9 where it says this can only be dispensed with a  
10 patient-specific prescription?

11 A. Well, so this says -- so the answer is this  
12 does not say those exact words, as you've stated. It  
13 does say, if you look at three bullets from the bottom,  
14 that it is compounded for your patients by pharmacists  
15 extensively trained in aseptic compounding.

16 The definition of compounding, right,  
17 certainly -- almost every definition of compounding  
18 means that the drug is -- if it's compounded, it's  
19 available for an individual patient by an individual  
20 prescription subject to a physician/patient  
21 relationship. So that's the basis of compounding.

22 Q. Okay. Is there a difference between aseptic  
23 compounding versus terminal sterilization?

24 A. I'd want to review that.

25 Q. Let me ask it differently. Do you know of any

1 difference between aseptic compounding and terminal  
2 sterilization?

3 A. I'd want to look at the various standards  
4 before I gave an opinion.

5 Q. Do you have any information at all whether the  
6 terms are synonymous or different, as you and I speak  
7 now? And the terms I'm talking about are aseptic  
8 compounding on one hand versus terminal sterilization on  
9 the other.

10 A. Yeah. So I, obviously, was involved in major  
11 sterility issues. And sterility is part of the Food,  
12 Drug and Cosmetic Act. I'd want to look at the code  
13 before I give an opinion.

14 Q. What is a class 10 microenvironment?

15 A. I'd have to look that up.

16 Q. How does a class 10 differ from an ISO 5 or an  
17 ISO 7 microenvironment?

18 A. Happy to look that up.

19 Q. Don't know without looking?

20 A. Again, I'd be happy -- those things are easy to  
21 answer your question. Again, happy to do that right now  
22 if you would like me to.

23 Q. What I'm interested in is whether you know  
24 without being prompted by looking at something else.

25 A. Sir, I'm here as an expert. And again, if you

1 look at my report, I don't go into this. You are asking  
2 me questions that are beyond my report. Happy to give  
3 you the answers, but in order to do that as an expert,  
4 I'd want to make sure. I'm not going to do stuff off  
5 the top of my head.

6 Q. Well, let me ask you this, Dr. Kessler: Can  
7 you tell me, without doing some research in writing,  
8 what the difference between an ISO 5 versus an ISO 7  
9 microenvironment is?

10 A. I'd have to look that up. I don't carry that  
11 in my head.

12 Q. All right. What and how is hyaluronidase used?  
13 Perhaps you can pronounce it better than I can.

14 A. Hyaluronidase.

15 Q. Yes. I like your pronunciation. It's on  
16 page 4.

17 How is that used and what is it used for?

18 A. So hyaluronidase -- I believe hyaluronidase is  
19 usually found in collagen. I believe it's a by-product,  
20 and is an enzyme that would affect collagen. Happy to  
21 look up the biochemistry.

22 Q. I'm not interested in this cellular action, but  
23 in what circumstances would a physician use  
24 preservative-free hyaluronidase?

25 A. So I would want to look at the label for

1 hyaluronidase. If you have it, give it to me. And the  
2 way we would determine that is look at the label for  
3 hyaluronidase and see what it would be indicated for.  
4 Again, I don't carry it in my head.

5 Q. Don't know?

6 A. I'd want to see what -- it's very easy to get  
7 the answer. We'd look at a label and see what the  
8 indications for use would be.

9 Q. Okay. Now, looking at the advertisement by  
10 NECC, page 4, the one we were just looking at, is there  
11 any statement that these products are only available  
12 with a patient-specific prescription?

13 A. Again, as I stated on the prior page, certainly  
14 any -- it says these are compounded.

15 Q. Right. But my question is specific. Is there  
16 a statement these products are only available with a  
17 patient-specific prescription? It's a yes or no.

18 A. So --

19 MR. ARBITBLIT: Objection. Objection. You  
20 interrupted his answer.

21 MR. GIDEON: Yeah.

22 MR. ARBITBLIT: It's not necessarily yes or no.  
23 So object to the question being misleading.

24 THE WITNESS: So if the definition of  
25 compounding includes patient-specific prescriptions as

1 it does, if drugs are available for compounding by  
2 patient -- I mean, compounding is done for  
3 patient-specific prescriptions. So those things are --  
4 certainly compounding includes patient-specific  
5 prescriptions.

6 So I would certainly say that anybody looking  
7 at this, if you know it's compounded and if you're -- if  
8 you're a professional, you should know that it's a  
9 patient-specific prescription.

10 MR. GIDEON: Q. I see. Is the language  
11 anywhere on this page where it says this product is  
12 only available with a patient-specific prescription,  
13 question mark?

14 A. On this page, it says it's compounded.

15 Q. Yeah.

16 A. Doesn't say -- have that language. I believe  
17 that if you look several pages later, it's there. But  
18 it's not -- it says it's compounded, which means  
19 patient-specific prescription.

20 Q. Right. Next page, page 5, starts off with  
21 Trouble Finding Preservative-Free Kenalog.

22 Do you see that?

23 A. Yeah, I do. It's triamcinolone, right?

24 Q. Right. It also states here, as it did on each  
25 one of the prior pages, USP 797 compliant, correct?

1           A. Yes.

2           Q. All right. Now, if NECC had actually complied  
3 with USP 797, the fungal meningitis outbreak never would  
4 have occurred; isn't that correct?

5           MR. CHALOS: Objection. Calls for speculation.

6           THE WITNESS: I wouldn't want to give an  
7 opinion on it.

8           MR. GIDEON: Q. Do you have an opinion on  
9 that question?

10          A. No.

11          Q. Sir?

12          A. No.

13          MR. GIDEON: Don, you said you wanted to take a  
14 break. This is an appropriate time to do so.

15          MR. ARBITBLIT: Before doing so, Counsel, I'd  
16 ask, for completeness, that you read paragraph G on  
17 page 10 of the document under the heading Dispensing.

18          MR. GIDEON: You'll get a chance to do so  
19 whenever you want to.

20          MR. ARBITBLIT: We'll do it now, then.

21          MR. GIDEON: Once we -- no, no. You don't get  
22 a chance in an expert's deposition to do an  
23 interrogation. You get the opportunity --

24          MR. ARBITBLIT: I --

25          MR. GIDEON: Wait a minute. Let me finish.



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1                   **MR. ARBITBLIT:** Sure.

2                   **MR. GIDEON:** You get an opportunity after I am  
3 finished.

4                   **MR. ARBITBLIT:** My understanding, sir, is that  
5 the rule of completeness applies at the time the  
6 question is asked about a document, and that you have  
7 not complied with it by omitting the text at page 10  
8 that is directly addressed to the series of questions  
9 you just asked the witness about pages 3 and 4.

10                  I believe that I am entitled to read that into  
11 the record now if you choose not to.

12                  **MR. GIDEON:** Okay. Well, I can't stop you from  
13 doing so today, but I don't think you have that  
14 prerogative. I don't recall asking him about page 10.  
15 But if you -- if you want to bring up page 10, then I  
16 guess I can't stop you from doing so. But this doesn't  
17 count against my time.

18                  **MR. ARBITBLIT:** This doesn't count against your  
19 time, but I will read into the record from the same  
20 document that counsel was using at page 10 under  
21 Dispensing as part of -- at page 9.

22                  **MR. GIDEON:** Excuse me, though, Don.

23                  **MR. ARBITBLIT:** Yes.

24                  **MR. GIDEON:** You are starting on page 10, but  
25 you are not even purporting to begin with the entire



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1 document which begins on page 9 with General --

2 MR. ARBITBLIT: I was just about to do that.

3 MR. GIDEON: -- General Overview of Policies &  
4 Procedures for Compounding Sterile Products at NECC.

5 MR. ARBITBLIT: Fair enough. That's just what  
6 I was about to do, Counsel.

7 Starting at page 9 of the document, General  
8 Overview of Policies & Procedures for Compounding  
9 Sterile Products includes paragraph G on the following  
10 page. Quote: Product is dispensed by patient-specific  
11 prescription only. There must be a specific  
12 practitioner-patient-pharmacist relationship to dispense  
13 to an individual patient or facility, end of quote.

14 MR. GIDEON: Okay. Now are you going to read  
15 the rest of pages 9 and 10?

16 MR. ARBITBLIT: I've read what I wanted to  
17 read. If you want to read more, you are welcome to do  
18 that.

19 MR. GIDEON: Okay. So the rule of completeness  
20 is not requiring you to spend your time going on the  
21 entire content of the document.

22 MR. ARBITBLIT: The rule of completeness does  
23 not mean that either of us has to read 33 pages into the  
24 record, Counsel, and you know that quite well.

25 MR. GIDEON: You got it. I agree.



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1                   All right. Let's take a short break and then  
2 we'll come back.

3                   While we are on break, to save some time, we're  
4 going to dictate the exhibit numbers on the documents  
5 that he gave us earlier. Okay?

6                   MR. CHALOS: Let's do that when we're all in  
7 the room together.

8                   MR. GIDEON: Then let's just do it right now  
9 before we take a short break.

10                  MR. CHALOS: That's fine. This counts against  
11 your time, by the way.

12                  MR. GIDEON: The article that's entitled FDA  
13 Tries to Compound the Compounding Rules is Exhibit 1244.

14                  The article, the FDA Mandate: Never Give Up,  
15 Never is Exhibit 1243.

16                  The -- you are covering the phone.

17                  THE WITNESS: I'm sorry. Are there people on  
18 the phone?

19                  MR. GIDEON: I don't know.

20                  The file folder that has the Franck's Lab  
21 documents is Exhibit 1242.

22                  The file folder that has material from Griscom  
23 to Hyde is Exhibit 1241.

24                  The ASHP material on methylprednisolone acetate  
25 injection is 1238.



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1                   FDA documents that deal with the Colorado Board  
2                   of Pharmacy cease and desist order that was sent to the  
3                   FDA are Exhibit 1237.

4                   The definition of adulteration is Exhibit 1235.

5                   And the Ota email correspondence is  
6                   Exhibit 1234.

7                   And then we have two additional documents that  
8                   are 1240 and 1237 (verbatim) that are the correspondence  
9                   from a lawyer Davis Wright and Tremaine to Dr. Miller.

10                  Okay?

11                  MR. ARBITBLIT: Okay.

12                  THE VIDEOGRAPHER: This is the end of disc  
13 No. 1, volume 1.

14                  We are off the record at 10:54 a.m.

15                  (Recess taken from 10:54 AM to 11:07 AM)

16                  THE VIDEOGRAPHER: This is the beginning of  
17 disc No. 2, volume 1.

18                  We are back on the record at 11:07 a.m. You  
19 may proceed.

20                  MR. GIDEON: Q. You said that you wanted  
21 to address something, Dr. Kessler?

22                  A. Yes.

23                  Q. What is it you want to address?

24                  A. Thanks. Just -- so if you go to look at  
25 page 82.

1 Q. Of what?

2 A. Of the transcript here.

3 THE REPORTER: It's my transcript today.

4 MR. GIDEON: Oh.

5 THE WITNESS: If you go to page 82 of it, the  
6 question is did Depo-Medrol the branded product from  
7 Pfizer also included an active ingredient -- may I do  
8 that -- called pick -- she -- I'll let you get that.

9 THE REPORTER: It will be edited later.

10 THE WITNESS: It will be edited -- but  
11 basically pick. That statement was made, and then she  
12 puts a question mark.

13 My answer was you would have to give me the  
14 label.

15 Let me just read for the record. The label  
16 that I have from Pfizer for Depo-Medrol shows that the  
17 ingredients includes methylprednisolone acetate,  
18 polyethylene glycol, polysorbate, monobasic sodium  
19 phosphate, diabasic sodium phosphate, and that the only  
20 preservative that's listed on the label that I have in  
21 front of me is benzyl alcohol. It says benzyl alcohol  
22 added as a preservative.

23 MR. GIDEON: Q. Want to see if I can ask  
24 you some questions that will elicit a direct answer.  
25 Very succinct answers.



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1                   **Were you consulted by the Massachusetts Board**  
2                   **of Registration and Pharmacy in connection with the**  
3                   **fungal meningitis outbreak?**

4                   A. No.

5                   Q. Were you consulted by the FDA in connection  
6                   with the fungal meningitis outbreak?

7                   MR. CHALOS: Object to the form.

8                   THE WITNESS: Depending on how you interpret  
9                   your question, the answer would be perhaps.

10                  MR. GIDEON: Q. By whom and when?

11                  A. So again, the only hesitation I have here is  
12                  I'm trying to think through the Department of Justice  
13                  request. So if you could -- you are asking me a  
14                  question -- I mean, again, just -- I need lawyers to  
15                  make sure we don't misstep here. Happy to answer it,  
16                  but I don't have in my own -- DOJ is not here, so I just  
17                  want to be careful here.

18                  So, I mean, again, I'm not sure how to answer  
19                  that without the advice of good counsel, meaning wise  
20                  people, in light of DOJ's letter.

21                  Q. That's your answer?

22                  A. The Department of Justice, sir, has made a  
23                  request of you --

24                  Q. Look, I know that. I don't want to spend my  
25                  time having you recap a letter that we --

1           A. Hold on a second --

2           MR. CHALOS: Wait a second --

3           THE WITNESS: May I finish my answer --

4           MR. GIDEON: I just asked, is that your answer?

5       It doesn't need -- you don't need to spend all my time  
6       talking about your thoughts.

7           THE WITNESS: Well, I mean, we --

8           MR. CHALOS: Hang on. I object to the  
9       admonition. It's not a question.

10          MR. GIDEON: Guys, one of the two of you should  
11       note the objections. You know that's a fundamental  
12       rule. It's either you, Mark, or it's you, Don.

13          MR. CHALOS: That's not true. That's not the  
14       way it works in MDL, C.J. Sorry to tell you, but --

15          MR. GIDEON: You're such an expert. I'm really  
16       appreciative of your commentary. And really, really  
17       thankful.

18          MR. CHALOS: I object to --

19          MR. GIDEON: What I'd like is a direct answer  
20       to my question --

21          MR. CHALOS: Hang on --

22          MR. GIDEON: -- which applies in every  
23       deposition in every setting.

24          MR. CHALOS: Let me interpose an objection.

25       We're not interested in your admonitions. If you have a



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1 question, you can ask it. If you don't like his answer,  
2 there's nothing you can do about that, Mr. Gideon.

3 MR. GIDEON: Well, there is something I can do  
4 about it, and I'll ask it again.

5 MR. CHALOS: Fair enough.

6 MR. GIDEON: Q. Were you consulted by the  
7 FDA in connection with the fungal meningitis  
8 outbreak? Question mark.

9 MR. CHALOS: And I object to that question on  
10 the grounds that we discussed earlier. There's a  
11 pending request from the Department of Justice that we  
12 treat -- that we are mindful of their assertions of  
13 privilege here. Dr. Kessler has expressed his concern  
14 that we may be getting very close if not over that line.

15 So object to the question.

16 MR. GIDEON: And do what?

17 MR. CHALOS: Period.

18 MR. GIDEON: Well, I want an answer to the  
19 question.

20 MR. CHALOS: Well --

21 THE WITNESS: So, just trying to get -- get to  
22 the question.

23 MR. GIDEON: Q. You'll see a really  
24 succinct question: Were you consulted by the FDA in  
25 connection with the fungal meningitis outbreak?



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1       Question mark.

2                   MR. CHALOS: Same objection.

3                   THE WITNESS: So I -- again, being respectful  
4       of the Department of Justice's admonitions to counsel  
5       here, I'm not sure I fully understand the scope -- what  
6       you mean by connection with the fungal meningitis  
7       outbreak. In connection with.

8                   So if -- because that's a -- I have had -- let  
9       me put on the record, I have had a conversation, right,  
10      with a senior FDA official, right, at a point in time,  
11      right -- again, I don't know whether it's within your --  
12      your time frame in connection with the fungal meningitis  
13      outbreak, right? But I have had a conversation with a  
14      senior FDA official, right?

15                  I don't know what the word "consulted" means,  
16       but we -- we had a conversation. Depends what you mean  
17       by "consulted" and "in connection with." So I've had a  
18       conversation with a senior FDA official.

19                  MR. GIDEON: Q. Okay. In connection with,  
20       related to, because of, dealing with the fungal  
21       meningitis outbreak or not?

22                  A. It's possible to interpret that conversation as  
23       within the scope of that question. Yes.

24                  Q. All right.

25                  A. But again --



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1 Q. When was this conversation with the senior FDA  
2 official?

3 MR. CHALOS: Hang on. Objection.

4 Are you finished with your answer, sir? You  
5 are entitled to finish it.

6 THE WITNESS: Yeah. I can only date it by  
7 events.

8 MR. GIDEON: Q. Fine.

9 A. I don't have a date.

10 Q. Sure. Date it by an event then.

11 A. So there were certain congressional hearings.  
12 There were multiple congressional hearings, and it was  
13 around that time.

14 Q. Was it in connection with, related to, or  
15 dealing with the testimony of FDA representatives before  
16 either the United States Senate or the United States  
17 House of Representatives?

18 MR. CHALOS: Same objections interposed before  
19 regarding the Department of Justice's request that we  
20 stay away from privileged materials.

21 THE WITNESS: Again, I don't fully -- just for  
22 the record, I don't fully understand the issue. I'm not  
23 asserting the privilege. I'm just trying to be  
24 respectful of DOJ's request.

25 The -- I'm not sure it was specifically about

1       testimony in your question. I mean, again -- but maybe  
2       you would interpret it as that conversation having to do  
3       with testimony. I remember a general conversation.

4                    MR. GIDEON: Q. I'm just asking the  
5       questions.

6                    I don't know -- so far, I don't know if you  
7       talked to anybody --

8                    A. Well, I just told you I did.

9                    Q. Okay. Well, who was it you talked to?

10                  A. So I'm going to ask --

11                  MR. CHALOS: Same objection.

12                  THE WITNESS: Yeah. I'm going to ask the DOJ  
13       and counsel and your judge, respectfully, to decide  
14       whether you want me -- whether the court wants me to do  
15       that. I'm happy to do that --

16                  MR. GIDEON: Q. Well, then go ahead and do  
17       it.

18                  A. Well, you're not the only -- there's others who  
19       have interests here.

20                  Q. I see.

21                  A. And I think, respectfully -- again, I'm only  
22       too happy to discuss this. But I've got to -- there was  
23       a letter that you received from the Department of  
24       Justice, and I -- obviously you want to honor that, I  
25       would assume, as well as you want to honor that.



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1           I'm happy to talk. I'm just trying to be  
2 thoughtful here on how we should deal with this. I've  
3 had a conversation with a senior FDA official that could  
4 be interpreted as having to do with FDA and the fungal  
5 meningitis outbreak. I don't know whether the  
6 United States government's interest, the court's  
7 interest, whether you want me -- whether I should answer  
8 that question or not.

9           Q. Are you declining to answer the question  
10 because of some uncertainty on your part about whether  
11 you should?

12          A. I -- again, I'm the last one to be --

13          Q. Please answer my question.

14          A. I am, sir. Please let me answer my -- let me  
15 fully answer.

16           Okay. I am not an expert. Okay? I am a  
17 student of, right, but I am not going to play lawyer  
18 here on deliberative process privileges of the  
19 United States government or on executive privilege, I  
20 mean, or on attorney-client, right?

21           They have put you on notice to be careful of  
22 conversations, right, that would relate to that. I'm  
23 pointing that out, right? I'm happy -- whatever the  
24 court would like me to answer, I'm only too happy to  
25 answer. But I think this needs to be discussed.



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1           I don't know who's on the phone, I don't know  
2 who's watching this streaming video, right? And I have  
3 concern -- and I think we have to do this thoughtfully.  
4 Again, happy to answer the question, I mean, if that's  
5 the right thing to do.

6           If you want to represent that it's the right  
7 thing to do in the Department of Justice's view, I'll  
8 take your representation.

9           Q. All right. I asked you a simple question, you  
10 have now told me three times about the reservations  
11 expressed by the justice department yesterday.

12           You've told me three times you're happy to  
13 answer but you are uncomfortable doing so.

14           All I want from you is a succinct answer. Are  
15 you declining to answer my question today until there is  
16 a ruling from Judge Zobel or a ruling from Judge Boal  
17 that clears away the uncertainty?

18           MR. CHALOS: Objection. Form and asked and  
19 answered.

20           THE WITNESS: I'm happy to answer the question  
21 today if you will assure me in asking the question, as  
22 an officer of the court, you, that there is no  
23 Department of Justice interest that could be asserted  
24 that I would be running up against.

25           If you give me that assertion, that it's fine



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1 for me to answer that question in view of the Department  
2 of Justice, I'm happy to answer that question.

3 MR. GIDEON: Q. Well, Dr. Kessler, you  
4 know, by dint of experience, that I cannot speak for  
5 the United States Department of Justice. You know  
6 that. You knew it when you asked me the rhetorical  
7 question.

8 MR. CHALOS: Hang on a second. Objection.  
9 That's not even a question. Object to the form.

10 THE WITNESS: But you are on notice that you  
11 should not go near deliberative process issues of the  
12 FDA. So you know what the rules are. I mean, you're  
13 the officer of the court. If you're confident that your  
14 question doesn't raise any issues -- I mean, again, I  
15 went to law school, but you are the lawyer here.

16 MR. GIDEON: Q. Yeah.

17 A. Okay. And I'm just telling you, I had a  
18 conversation, I recall a conversation, you are pushing  
19 me to answer that question. And I think it would be  
20 wise to make sure, before you go further, to consult  
21 with the Department of Justice.

22 I'm happy to have you do that today. Pick up  
23 the phone and call and do that. But please work that  
24 out, right, so we can all -- I'm happy to answer that  
25 question.

1           Q. We'll do two things. We don't need to spend  
2 any more time on this particular point. We'll get ahold  
3 of Glass, David Glass. We'll get the court reporter to  
4 give him a specific question at a break that he can tell  
5 us whether or not he asserts an objection or not. If he  
6 does, we'll take this up with Judge Boal. If he  
7 doesn't, I'll expect an answer to the question. Simple.  
8 Simple solution.

9           A. Fair.

10          Q. Okay.

11          A. Thank you.

12          Q. Were you consulted by the United States House  
13 of Representatives or the United States Senate with  
14 respect to the legislation passed in 2013 designed to  
15 reform control and management of compounders?

16          A. I don't recall.

17          Q. I suspect you are aware that the Senate health,  
18 education, labor and pension committee is currently  
19 looking at funding for the NIH budget for the FDA; are  
20 you aware of that?

21          A. I am aware generally, yes.

22          Q. Okay. And I assume you are also aware of the  
23 fact that the Senate labor committee, the one I just  
24 mentioned to you --

25          A. That I used to work for.

1           Q. -- chaired by, now, Lamar Alexander of  
2 Tennessee, is looking at changing the rules regarding  
3 FDA jurisdiction over lab testing equipment and the  
4 extent of jurisdiction over medical software. You are  
5 familiar with that, aren't you?

6           A. I'm aware that there are multiple bills pending  
7 in the Senate. If you have any of those draft bills,  
8 please give them to me so we can be specific. I know  
9 there are a whole host. There are many FDA issues that  
10 are currently under consideration.

11          Q. The question is, have you been consulted by the  
12 Senate health, education, labor and pension committee on  
13 any of the points I just brought up?

14          A. On medical software or --

15          Q. Lab testing equipment.

16          A. I don't believe by the Senate health committee,  
17 no.

18          Q. When were you engaged to participate in this  
19 specific litigation? "When" is the operative question.

20          A. The word that I'm having a hard time is  
21 "engaged." I can tell you when I was contacted.

22          Q. All right. That's what I mean. When were you  
23 asked to participate, hired on, asked to get involved?  
24 When?

25           MR. CHALOS: Objection. Form.

1                   THE WITNESS: I think the first conversation I  
2 had -- don't hold me to it -- may have been -- may have  
3 been summer 2014, but don't hold me to that date. I  
4 don't have a great recollection.

5                   MR. GIDEON: Q. Well, is there something  
6 we should look at so you can refresh your  
7 recollection and tell us when you were actually  
8 asked to be involved?

9                   A. You'd probably have to look in my brain or look  
10 at the person who talked to me. I think it was a  
11 conversation. I don't think there was anything else.

12                  Q. Who is the person I should look at who talked  
13 to you? Should I look at Don?

14                  A. If that's permissible under the federal rules.

15                  Q. Is it Don that engaged you?

16                  A. I -- you are using the word "engaged." I --  
17 again, may I -- am I free under the federal rules to  
18 tell you who I've communicated with?

19                  Q. Of course.

20                  A. So if that is fine, then, yes, I had a  
21 conversation with Mr. Arbitblit, I believe, around 2014.

22                  Q. All right. And Mr. Arbitblit is the gentleman  
23 who is here today that I was referring to as Don?

24                  A. Yes.

25                  Q. Okay. Was the telephone call from



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1       Mr. Arbitblit to you in the summer of '14 the first time  
2       you had worked with him?

3           A. No, I don't believe so.

4           Q. Let's take a look at Exhibit B to your  
5       report --

6           A. Sure.

7           Q. -- which is a listing of litigation-related  
8       involvements.

9           A. If you want to just see, it is --

10          Q. I'm going to hand you one. Don't worry about  
11       it.

12          A. Thanks.

13          Q. We're going to hand you one.

14           And for the purposes of efficiency, I'm going  
15       to refer to the firm you are working with today as Lieff  
16       Cabraser. There may have been name changes over the  
17       years, but that's the firm I'm referring to.

18           Mr. Arbitblit is a member of Lieff Cabraser,  
19       correct?

20          A. Yes.

21           (Whereupon, Exhibit 1248 was marked for  
22       identification.)

23          MR. GIDEON: Q. Okay. This is  
24       Exhibit 1248, and it's Exhibit B to your testimony?

25          A. Yes.

1           Q. The first thing I want to do is for you to tell  
2 us on the bullet points in which of those cases were you  
3 employed, contacted to participate in the case, by  
4 Mr. Arbitblit or one of his colleagues at Lieff  
5 Cabraser?

6           A. Give me a second to go through this list to  
7 find that.

8           Q. Sure.

9           MR. CHALOS: Object to the form.

10          MR. GIDEON: What's wrong with the question?

11          MR. CHALOS: It's compound. It says in which  
12 of those cases were you employed, contacted to  
13 participate in the case. I think those are two  
14 different concepts.

15          MR. GIDEON: Well, we'll see if we can bridge  
16 that gap.

17          MR. CHALOS: That's a good idea.

18          MR. GIDEON: Q. Ready?

19          A. Yeah. Thank you.

20          Q. In which of the cases were you contacted to  
21 participate by Lieff Cabraser or one of the lawyers in  
22 that office?

23          A. My recollection is that I was contacted in the  
24 Yaz case by Mr. Arbitblit.

25          Q. Okay. This is six bullet points down, the Yaz

1 and Yasmin Marketing Sales Practices & Products  
2 Liability Litigation?

3 A. Yes. My recollection is I was contacted by  
4 him.

5 Q. Did you end up working with him in that  
6 litigation or did you work principally with someone  
7 else?

8 A. There were multiple attorneys involved in that  
9 case.

10 Q. Okay.

11 A. That case settled.

12 Q. Any others?

13 A. So the answer is -- I just want to be complete.  
14 I'm going to go a little beyond your question, if I may,  
15 okay, I mean, so you have the full -- so I don't  
16 misspeak here, right?

17 I believe the -- there's two other cases that  
18 come to mind where Mr. Arbitblit may have been involved  
19 in, but I don't believe he contacted me.

20 Q. Okay.

21 A. But again, of one I'm sure he didn't contact me  
22 because it was the attorney general of Louisiana where I  
23 was retained on, but I believe Mr. Arbitblit worked on  
24 that. And there may have been -- and --

25 Q. Which one was that on this list?

1           A. So there was -- it was State v. -- if you go  
2 down, State v. Merck, that's the attorney general of  
3 Louisiana.

4           Q. And Mr. Arbitblit, according to your  
5 recollection, worked on State versus Merck & Company?

6           A. Yes, that's my recollection.

7           Q. Okay. And is there another one where you think  
8 you worked with Mr. Arbitblit?

9           A. Yeah. Again, I don't remember who -- I mean,  
10 that one I know Mr. Arbitblit did not contact me on.

11          Q. Okay.

12          A. I can recall. But I believe Mr. Arbitblit was  
13 involved in Actos, but I don't recall who contacted me.

14          Q. Which bullet corresponds with that reference?  
15 The one that's near -- two-thirds down?

16          A. Yes, sir.

17          Q. Okay. In the Western District of Louisiana,  
18 filed 12/29/11?

19          A. Yes, sir.

20          Q. Okay. Now, I didn't mean to limit my question  
21 to Mr. Arbitblit. I intended to expand it to all the  
22 members of his law office, Lieff Cabraser, irrespective  
23 of which office it may be. Are there any other cases  
24 where Lieff Cabraser worked with you on this Appendix B?

25          A. Let me look. Those are the ones that I see

1 sitting here.

2 Q. Okay.

3 A. That's the ones -- that's what comes to mind.

4 Q. Now, I just want to take them item by item so  
5 we get a snapshot of what the case was about from your  
6 view.

7 On the Zoloft Product Liability Litigation that  
8 was filed April 17th, 2012, were you testifying on  
9 behalf of the people suing the manufacturer of Zoloft?

10 A. Yes.

11 Q. And who was the manufacturer of Zoloft that you  
12 were offering opinions about?

13 A. I'd have to -- I believe it was Pfizer.

14 Q. Okay. And at the time that Pfizer developed  
15 Zoloft, was Pfizer an FDA-registered manufacturer?

16 A. Certainly.

17 Q. Did you express the opinion that Pfizer, as an  
18 FDA-registered manufacturer, had acted improperly?

19 A. We'd have to pull that. You would have to look  
20 at that.

21 Q. You don't recall what the critique was?

22 A. I --

23 Q. Sir? You don't recall --

24 A. I'm just double-checking that it's Pfizer.

25 Just to be -- just so that I have my head -- just give

1 me one second.

2           That case had to do with birth defects and what  
3 the label said about -- and whether it was appropriately  
4 categorized as a category D drug, whether there was  
5 human evidence. And there was human evidence, and I  
6 said that.

7           Q. And the essence of the critique was that the  
8 manufacturer of Zoloft had not shared with the FDA the  
9 data reflecting that the product could be harmful to the  
10 unborn, correct?

11          A. No. I don't think that was what the critique  
12 was.

13          Q. Well, what was it, then?

14          A. So I -- well, we'd have to pull the actual  
15 opinions, and I don't have that with me.

16          I think that the critique was that the -- that  
17 the human evidence of risk to the fetus was not  
18 disclosed to patients and physicians in the label. Not  
19 to -- not as you said.

20          Q. All right. The second bullet point, In re  
21 Risperdal -- Risperdal. Excuse me. Risperdal is  
22 manufactured by Johnson & Johnson, isn't it?

23          A. Janssen Pharmaceutica is owned by Johnson &  
24 Johnson.

25          Q. What was the critique of the division of

1       Johnson & Johnson in re Risperdal?

2           A. This had to do with boys growing breasts and  
3       the issue of both the -- as you know, there was a --  
4       there was a criminal trial with off-label prosecution  
5       for Janssen. I believe an off-label promotion.

6           So it had to do with both the off-label  
7       promotion, that illegal activity, as well as whether  
8       Janssen failed to disclose data in the scientific -- I  
9       mean, in its studies.

10          Q. Uh-huh. You offered opinions critical of the  
11       division of Johnson & Johnson in that case, didn't you?

12          A. I offered the opinions, the facts supported.

13          Q. I am not -- I am not asking you whether you  
14       felt your opinions were justified or somebody didn't.  
15       I'm just trying to determine which side of the  
16       litigation you were on, Dr. Kessler.

17           Were you testifying on behalf of a patient  
18       suing Janssen or were you testifying on behalf of  
19       Janssen?

20          A. On behalf of the patient.

21          Q. All right. Let's go to the third bullet point,  
22       Wells versus Allergan, Drake versus Allergan, two cases  
23       listed together. What was the essence? What was the  
24       issue in these cases?

25          A. So the issue was children getting botulism from

1       Botox.

2           Q. Were you testifying on behalf of a family suing  
3 Allergan or were you testifying on behalf of Allergan?

4           A. I was testifying on behalf of the families  
5 where the children got botulism.

6           Q. And at the time Allergan made the products in  
7 question, Allergan was an FDA-registered manufacturer,  
8 correct?

9           A. Yes.

10          Q. Let's go to the fourth item, fourth bullet  
11 point, C.R. Bard, Inc., Pelvic Repair System Products  
12 Liability Litigation. Did this deal with the pelvic  
13 sling?

14          A. Pelvic mesh.

15          Q. And in that case were you testifying on behalf  
16 of patients suing C.R. Bard?

17          A. Yes.

18          Q. And at the time C.R. Bard made the pelvic mesh,  
19 was C.R. Bard an FDA-registered manufacturer?

20          A. I'm sure.

21          Q. Okay. Then the next bullet point is SB versus  
22 Ortho-McNeil-Janssen Pharmaceuticals, Risperdal. Ortho,  
23 McNeil and Janssen are all wholly-owned subsidiaries of  
24 J&J, aren't they?

25          A. Yes.



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1           Q. Were you testifying on behalf of patients suing  
2 Ortho, McNeil and Janssen?

3           A. Yes.

4           Q. Ortho, McNeil and Janssen were all  
5 FDA-registered manufacturers, correct?

6           A. Yes.

7           Q. In re Yaz & Yasmin Marketing Sales Practice &  
8 Products Liability Litigation. Yaz and Yasmin were  
9 contraceptives, weren't they?

10          A. Drospirenone. Yes, sir.

11          Q. And who was the company that made those  
12 products?

13          A. I'm just double-checking so I can get -- my  
14 recollection is it's Bayer. Let me just double-check  
15 that for the record.

16               Yes, it's Bayer HealthCare Pharmaceuticals.

17          Q. Was Bayer HealthCare Pharmaceuticals an  
18 FDA-registered manufacturer when Yaz and Yasmin were  
19 made?

20          A. Yes.

21          Q. And what was your critique of Yaz and Yasmin?

22          A. Again, I think it had to do with off-label  
23 activity as well as disclosure of -- the failure to  
24 disclose data that the company had.

25          Q. Failure to disclose data the company had before

1 seeking approval?

2 A. We'd have to pull the report. I don't want to  
3 misspeak here.

4 Q. All right. In re Flonase Antitrust Litigation,  
5 who engaged you in that case? Which side of the  
6 litigation?

7 A. There were corporate entities that engaged me.  
8 These were payers who paid for drugs. This was  
9 antitrust litigation.

10 Q. And your role was to support people who were  
11 opposing a merger?

12 A. No. This was complicated citizens' petition  
13 language, generic -- generic drugs, et cetera. I was  
14 testifying on a pretty narrow issue.

15 Q. And what was the narrow issue?

16 A. Again, about FDA citizens' petition, the  
17 regulation of generic drugs.

18 Q. I see. Okay.

19 Well, did you offer substantive testimony  
20 regarding the scope of FDA regulation of generic drugs  
21 in that case?

22 A. I think that would be probably fair. We'd have  
23 to go back and look at the testimony.

24 Q. That was the Eastern District of Pennsylvania?

25 A. Right.

1 Q. Okay. Is Pharmathene versus Siga Techs, Inc. a  
2 commercial case?

3 A. Yes.

4 Q. Does that also deal with market share,  
5 antitrust considerations?

6 A. No. I believe it had to do with patent. I was  
7 hired by Siga Technologies, the -- I was hired by the  
8 drug manufacturer.

9 Q. Commonwealth versus Merck & Company, Kentucky  
10 Circuit Court, September 28, 2009 and Utah; what product  
11 was at issue in that litigation?

12 A. That was I was retained by the attorney general  
13 of the state. And that was Vioxx.

14 Q. Vioxx. Okay.

15 And you were testifying on behalf of  
16 individuals suing Merck & Company?

17 A. No.

18 Q. No?

19 A. I was testifying on behalf of the attorney  
20 general.

21 Q. And the testimony you offered at the request of  
22 the attorney general was what?

23 A. I mean, it had to do with the science  
24 underlying Vioxx.

25 Q. Did it have to do with the risk of myocardial

1 infarction in individuals taking Vioxx?

2 A. Yes.

3 Q. And did you offer the opinion that Merck &  
4 Company had not acted appropriately with respect to the  
5 risk of myocardial infarction?

6 A. There was specific -- I'd want to look at that  
7 report, but there were specific representations of the  
8 company that were in question.

9 Q. Your testimony was critical of Merck & Company?

10 A. My testimony dealt with that science. And  
11 again, happy to come back and tell you what those  
12 opinions were. I believe that case settled, so I don't  
13 know what's public record or not.

14 Q. Merck & Company was an FDA-registered  
15 manufacturer at the time that it's -- that it developed  
16 and obtained permission to market Vioxx in the  
17 United States, wasn't it?

18 A. Yes.

19 Q. Okay. Next one is Commonwealth Care Alliance  
20 versus AstraZeneca Pharm, L.P. Is this a commercial  
21 dispute over insurance payments or market share?

22 A. I believe this is -- this is also -- I'd want  
23 to go back. I believe this was an antitrust case.

24 Q. Smith & Nephew, Inc. versus N.H. Insurance  
25 Company in the Western District of Tennessee. What was

1 the issue there?

2 A. I was retained by counsel for the defendants.

3 Again, it had to do with legality of conduct.

4 Q. The legality of Smith & Nephew, Inc.'s conduct?

5 A. Yes.

6 Q. Was there a contention by N.H. Insurance  
7 Company that they shouldn't have to pay for something  
8 because Smith & Nephew had done something  
9 inappropriately?

10 A. Again, I want to be a little careful. I don't  
11 know what is confidential there and what's not. So we'd  
12 want to check with counsel before I answer.

13 Q. Who was the attorney that engaged you in the  
14 Smith & Nephew case?

15 A. Frost, Todd, Brown.

16 Q. In Kentucky?

17 A. Yes.

18 Q. Who in particular at Frost Todd engaged you?

19 A. Laurie Hammond.

20 Q. Say it one more time.

21 A. I believe Laurie Hammond.

22 Q. And who was the attorney for Smith & Nephew,  
23 Inc.?

24 A. I don't recall.

25 Q. Okay. In re Neurontin Marketing, Sales

1       **Practices & Products Liability Litigation, the District**  
2       **Court of Massachusetts.**

3           A. Again, legality of conduct, off-label promotion  
4       by Pfizer, certain corporate entities suing Pfizer for  
5       that off-label conduct.

6           Q. Right. And Pfizer, again, was FDA registered  
7       at the time they carried out the conduct in question,  
8       weren't they?

9           A. Yes.

10          Q. Did you work with Lieff Cabraser in the  
11       Neurontin Marketing Sales Practices & Products Liability  
12       Litigation?

13          A. That does not come to mind, no.

14          Q. Brown versus American Brands, is that a tobacco  
15       case?

16          A. That is.

17          Q. In re Actos, who was the manufacturer of Actos?

18          A. I believe it was Takeda.

19          Q. Takeda. Japanese pharmaceutical firm?

20          A. Yes.

21          Q. And the contention is that Actos triggered an  
22       unacceptable incidence of bladder cancer; isn't that  
23       right?

24          A. There was a statistically significant increase  
25       in bladder cancer if you did the analysis beginning in

1       2002, and that was never reported by -- that was never  
2       reported by the company.

3           Q. Was Takeda an FDA-registered manufacturer when  
4       they developed Actos and obtained permission to market  
5       that product in the United States?

6           A. Again, I would assume so. That company was  
7       acquired, I believe. I just have to go back and look.  
8       I believe that's correct.

9           Q. All right. The -- this is one of the cases  
10      where you said that you worked with or were contacted by  
11      Mr. Arbitblit.

12       A. Arbitblit.

13           MR. GIDEON: I'm sorry, it's hard for me to  
14       pronounce and I don't know why. Arbitblit. I've got it  
15       down now.

16           MR. ARBITBLIT: You are not the first.

17           MR. GIDEON: Q. Did you testify on behalf  
18      of patients who were suing Takeda in that case?

19       A. Yes. There was a \$7 billion verdict.

20       Q. Mr. Arbitblit did very well in that case,  
21       didn't they? Did he share any of those proceeds with  
22       you after you delivered a \$7 billion verdict?

23           MR. CHALOS: Object to form.

24           THE WITNESS: It was a \$6 billion verdict, and  
25       no.

1                   MR. GIDEON: Q. Next, Brown versus

2 RJ Reynolds Tobacco. Tobacco case?

3                   A. Yeah, I believe -- yes, it's a tobacco case.

4                   Q. I'm going to go down to Cabana versus Stryker.

5 Were you testifying on behalf of someone suing the

6 device manufacturing company Stryker?

7                   A. Yes.

8                   Q. And what was your critique of Stryker?

9                   A. Again, I don't know whether that is public or  
10 not. You'd -- I would want to -- I'd want you to  
11 contact the counsel. I believe that case settled, so I  
12 don't know what is public, sir.

13                  Q. You represent -- you articulated the interest  
14 of the plaintiff or the defendant in that case?

15                  A. I represented the interests of me, in that I  
16 told what the science was.

17                  Q. Who engaged you, plaintiff or defendant?

18                  A. Plaintiffs. Thank you.

19                  Q. Who paid you, plaintiff or defendant?

20                  A. It was a plaintiff in that case.

21                  Q. Who was the lawyer, then, that engaged you so I  
22 can check with him and see if it's okay to talk to you  
23 about what you did in that case?

24                  A. I'll get you the name. It's --

25                  Q. Just make yourself a note, and when it comes to



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1 you --

2 A. Yeah, it's -- it's Estephan -- it's -- first  
3 name is Estephan. Cynthia Garber was also, I think,  
4 involved. But it was Estephan. I'd be happy to get you  
5 the name.

6 Q. Sure. That's fine. Then the next one down is  
7 re Fosamax litigation.

8 A. That was a narrow issue about preemption.  
9 And -- in Fosamax. But it was whether, in fact, certain  
10 actions were preempted under a statute.

11 Q. Were you offering testimony on behalf of a  
12 patient suing the manufacturer of Fosamax claiming that  
13 the state law claims were not preempted by federal law?

14 A. Yes. It was under preemption. And, again, the  
15 nature of those claims.

16 Q. And you were engaged by the plaintiff in that  
17 case?

18 A. Yes.

19 Q. In any -- has there been any personal injury  
20 case in the last six years where you testified on behalf  
21 of a defendant?

22 A. Personal injury, no. But other cases I've  
23 testified on behalf of defendants.

24 Q. Well, now let's look at the affidavits here.  
25 The DePuy --

1           A. That's actually not true.

2           Q. Which one of these, where there's a claim of  
3 personal injury, death, physical suffering, where you  
4 testified on behalf of a defendant?

5           A. The second one.

6           Q. The Risperdal?

7           A. I'm sorry. I apologize. I'm looking at the  
8 bottom three, sir.

9           Q. Well, the bottom three are just affidavits or  
10 sworn expert statements.

11          A. They're sworn statements, but that was on  
12 behalf of the defendant, in that -- where the defendant  
13 was being sued.

14          Q. Which case?

15          A. The Cordero v. Endoscopy. I was testifying on  
16 behalf of the endoscopy center.

17          Q. What testimony were you offering? What was the  
18 subject matter of your opinion testimony in that case?

19          A. Adverse events. Adverse event reporting.

20          Q. Okay. Under the MedWatch system?

21          A. Exactly.

22          Q. Were you offering any testimony regarding how  
23 to perform an endoscopic procedure? On the techniques  
24 of endoscopy?

25          A. Not that I recall.

1           Q. On the first affidavit, the ASR Hip System  
2 Cases, were you offering opinions critical of that  
3 subsidiary of Johnson & Johnson?

4           A. There was an issue there, I believe, about  
5 public disclosure of whether certain documents in the  
6 public interest should be disclosed or not. I think  
7 that was the matter.

8           Q. Did this --

9           A. I don't recall that.

10          Q. Did this particular hip system case deal with  
11 petrochemical -- a failure to clean off petrochemical  
12 substances on the acetabular cup?

13          A. No, I don't believe so.

14          Q. And what was the issue in Jenkins versus  
15 Medtronic?

16          A. I apologize. I don't remember.

17          Q. It's also in the Western District of Tennessee?

18          A. Yes.

19          Q. Were you engaged by Frost Todd in that case  
20 too?

21          A. I don't believe that was the case. And I  
22 apologize, I don't remember that.

23          Q. Are there any other cases that constitute  
24 affidavits or sworn statements or testimony at trial or  
25 by deposition other than what we've just covered in this

1 exhibit?

2 A. This is what comes to mind. Actually, hold on  
3 one second. Let me just think of something.

4 So there may be a case subsequent to this  
5 report that I may have testified in.

6 Q. This report was sent to us in December of 2015.  
7 Have you testified in the last 90 days?

8 A. I believe I may have one case, I believe.

9 Q. Where?

10 A. In deposition.

11 Q. In San Francisco, but where was the case  
12 pending?

13 A. I believe it's St. Louis.

14 Q. What was the style of the case? The who sued  
15 whom?

16 A. It's a plaintiff -- it's a joint -- it's a  
17 bellwether case on Depakote.

18 Q. And who is the manufacturer of Depakote?

19 A. Give me a second so I can get it.

20 Q. Are you referring to Google again?

21 A. Well, yeah. I just want to make sure I get it  
22 exactly right. Just give me a second. I have it in my  
23 head, but I just -- let me -- I'll be happy to do that  
24 at the next break and give it to you.

25 Q. All right. Did you testify on behalf of the

1 manufacturer of Depakote or on behalf of people suing  
2 Depakote?

3 A. It was on behalf of the plaintiffs.

4 Q. And who engaged you?

5 A. There is a -- I mean, there's -- I believe  
6 there's an MDL that Janet Arbitblit and Williams Keker  
7 (phonetic).

8 MR. ARBITBLIT: Sorry --

9 MR. GIDEON: Q. Is that -- Janet  
10 Arbitblit, is that Don Arbitblit's wife?

11 A. No, no, no.

12 MR. ARBITBLIT: Janet Abaray --

13 THE WITNESS: Janet Abaray. I'm sorry. Now  
14 you have me confused.

15 MR. ARBITBLIT: My wife would not be happy to  
16 hear that there's a Janet Arbitblit.

17 THE WITNESS: Yes, I'm sorry. I apologize.  
18 Now you have me --

19 MR. GIDEON: Q. Putting aside the humor  
20 now, who was it that asked you to be involved in  
21 that case?

22 A. I think it's Janet Abaray.

23 Q. Could you spell the last name for us.

24 MR. ARBITBLIT: A-B-A-R-A-Y.

25 MR. GIDEON: Q. And where does she



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1 practice?

2 A. I believe somewhere in Ohio, if I'm right.

3 Q. And is there, as you said, an MDL on damages  
4 associated with the use of Depakote?

5 A. There is -- this -- again, this is birth  
6 defects. This is a well-known teratogen.

7 Q. And you offered opinions in that deposition  
8 that were critical of the manufacturer of Depakote?

9 A. I offered an opinion of -- based on the  
10 scientific evidence that the congenital risks -- total  
11 congenital malformations was known as of a certain date.

12 Q. And that the --

13 A. And that there was also illegal -- again, there  
14 was illegal conduct. There was a consent decree against  
15 the pharmaceutical company for off-label marketing.

16 Q. And was this -- was this manufacturing company  
17 an FDA-registered manufacturer that carried out this  
18 illegal activity?

19 A. Yes.

20 Q. FDA registration, then, does not assure that  
21 the public will receive safe, uncontaminated products,  
22 does it?

23 A. No. There is no guarantee here. Right? It's  
24 a system of regulation. But as we all know, it is  
25 the -- there are no guarantees. My predecessor, Don

1 Kennedy, taught me that -- who was president of Stanford  
2 subsequently, as Don said, all FDA really can do is  
3 create incentive for companies and individuals to act  
4 appropriately.

5 Q. Okay. But among the incentives, I think I  
6 recall from your report that during your tenure as  
7 commissioner of FDA, you created an office, division or  
8 section, I don't want to get hung up on the term, of  
9 criminal investigations, correct?

10 A. OCI. Office of criminal investigations. Yes.

11 Q. So what I said is correct?

12 A. It's an office -- yes, I created that office.

13 Q. In what year? Well, you were there '90 to '97,  
14 so when was it during your tenure?

15 A. I don't know exactly. It was pretty early on.

16 Q. Okay.

17 A. And your word creation is -- leaves some, you  
18 know, exactly when I, you know, to implement.

19 But I came up with the idea and I put the idea  
20 into implement -- and it was probably '92 or about that  
21 time.

22 Q. Okay. During the years that you were  
23 commissioner of the Food and Drug Administration, you  
24 had the authority to call upon manufacturers to enter  
25 into a moratorium on sale of products in the

1       United States, didn't you?

2            MR. CHALOS: Object to the form.

3            THE WITNESS: I would not -- I did that in one  
4 instance, based on -- let me tell you what the authority  
5 was. This was a device that was on the market as a  
6 preamendments class 3 device. And the manufacturer was  
7 allowed to market the device, knowing that it would have  
8 to supply safety and efficacy data when the FDA called  
9 for it. That's the way Congress created the statute.

10           When we called for the data, there was no data.  
11 The manufacturers didn't have -- they had never studied  
12 the device, and yet the market -- the device had been on  
13 the market for several decades and people were using the  
14 device.

15           What I did was I could have -- based on the  
16 fact that the device then became a -- I mean, shipped in  
17 interstate commerce without an approved indication, I  
18 thought that the best way, in light of certain  
19 controversy, was just to basically say time out. Let's  
20 see if we can figure out what that data is -- are. So I  
21 called for a moratorium.

22           MR. GIDEON: Q. Okay.

23           A. Based on that authority. Because it was a  
24 preamendments class 3 device for which they did not  
25 submit any data.



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1           Q. And you called for a moratorium with respect to  
2 a product widely referred to as a silicone breast  
3 implant?

4           A. Yes.

5           Q. In addition to the authority to call for a  
6 moratorium on a product, the FDA had the authority, if  
7 someone was, in the view of the FDA, violating the law,  
8 to seek an injunction to enjoin them from improper  
9 activity, correct?

10          MR. CHALOS: Object to the form.

11          THE WITNESS: There are a number of remedies  
12 under the Federal Food, Drug and Cosmetic Act.

13          MR. GIDEON: Q. Injunction is one of them?

14          A. Injunction is one of them for violations.

15          But understand how that works. FDA can't just  
16 enjoin. FDA has to go into a court and ask a court to  
17 enjoin.

18          Q. And FDA has to go into a court and convince the  
19 court to enter an injunction, correct?

20          A. Yes.

21          Q. All right. FDA also had the authority to issue  
22 alerts to consumers and to healthcare providers,  
23 correct?

24          MR. CHALOS: Object to the form.

25          THE WITNESS: Concerning what?

1                   MR. GIDEON: Q. Well, let's say, for  
2 example, do you recall a concern at FDA when you  
3 were commissioner about the use of transdermal  
4 fentanyl patches?

5                   A. My -- the concern that I remember with regard  
6 to fentanyl was the fentanyl lollipop. That was the one  
7 that I remember. I'm not saying you are wrong. I'd  
8 have to refresh my recollection. But the -- there was a  
9 fentanyl product that was being manufactured as a  
10 lollipop --

11                  Q. For children?

12                  A. -- anesthesia. Sorry?

13                  Q. For children?

14                  A. For children. And that's the one that I was  
15 intimately involved in.

16                  Q. And what did the Food and Drug Administration  
17 do about the fentanyl lollipop while you were the  
18 commissioner?

19                  A. So I think we put significant restrictions on  
20 how and when it can be used was my recollection.

21                  Q. And required a black box warning?

22                  A. I'm sure, again, this was -- this was as part  
23 of the new drug process.

24                  I mean, just so -- for the record, you're  
25 asking me about questions about, for example, in

1 fentanyl, you are dealing with a new drug, right? I  
2 mean, just for the record, you have the ability to do  
3 certain things for new drugs and then there are old  
4 drugs. And one of the questions, obviously, in this  
5 matter is whether compounding makes a drug a new drug,  
6 whether it's a new drug or whether it's an old drug.

7 Q. Okay. We're talking about remedies available  
8 to the Food and Drug Administration.

9 A. But it's remedies -- please understand it  
10 depends --

11 Q. I didn't finish my question.

12 A. Okay. Sure. I'm sorry. I apologize, sir.

13 Q. We were talking about remedies available to the  
14 Food and Drug Administration in addition to insisting  
15 upon a moratorium, under the circumstances you  
16 described, seeking an injunction, issuing warnings or  
17 notices to the public. What other remedies were  
18 available?

19 A. Let's put a footnote there. Those remedies  
20 depend on the regulatory class -- regulatory status of  
21 the product. So I wouldn't want to answer your question  
22 that you can do a moratorium in any instance. I  
23 wouldn't want to say you can put a black box on any  
24 instance.

25 I mean, those labeling requirements, for

1 example, I mean, apply to new drugs. So let's just be  
2 careful which remedies apply to which category of  
3 products.

4 Q. Okay. Now, isn't it true, and hasn't it been  
5 true, throughout the time you began at FDA in 1990, and  
6 up to the current date, that FDA does not approve a  
7 chemical compound, FDA approves a drug for an intended  
8 use?

9 A. I --

10 MR. CHALOS: Object to the form.

11 THE WITNESS: I've stated that.

12 MR. GIDEON: Q. Is it true or not?

13 A. So it is true with regard to new drugs, sir,  
14 under section 505, right?

15 Then we can deal with old drugs. That would  
16 not be applicable to old drugs.

17 Q. Okay. Was Depo-Medrol approved by the FDA for  
18 epidural injection in the time frame 2010 to 2012?

19 A. I don't believe Depo-Medrol ever was approved  
20 for steroid injection. I believe the use is an  
21 off-label use.

22 Q. Was Kenalog, a branded product, made by  
23 Bristol-Myers, approved for epidural steroid injection  
24 2010 to 2012?

25 A. So I believe the answer is no. But again, to

1       be thorough here, if you want to ask me what those  
2       things are approved for, if you can just hand me the  
3       label. We should be precise here, but I believe on my  
4       recollection of the label, the answer is no.

5           Q. There is a difference, isn't there, between  
6       off-label and against label use?

7           MR. CHALOS: Object to the form.

8           MR. GIDEON: Q. The question is just is  
9       there a difference. And if there isn't, you can say  
10      no. If there is, say yeah and then we'll talk about  
11      it some more.

12          MR. CHALOS: Objection to form.

13          THE WITNESS: I don't know what you mean  
14      exactly by "against label."

15          MR. GIDEON: Q. Well, for example, the  
16      Kenalog label specifically prohibits using that  
17      product for epidural steroid injections, doesn't it?

18          A. I need to see the label, please.

19          Q. Why don't you pull it up on your computer.  
20      It's right in front of you. Kenalog, Bristol-Myers.

21          A. Happy to do that, sir.

22          Kenalog 10, let's see if I have it.

23          Q. I'm not sure anybody can hear you speaking with  
24      your hand up, Dr. Kessler.

25          A. Let me see if I can get the official



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1       Bristol-Myers answer.

2                  I don't have the official -- I'm getting a  
3                  generic cite. If you can just hand me the label so I  
4                  can have the prescribing information, or if anyone has a  
5                  copy of the PDR.

6                  Q. We'll get it for you. We'll get it for you.

7                  A. I appreciate it.

8                  Q. Is there a difference between off-label versus  
9                  against-label use?

10                 MR. CHALOS: Objection to form.

11                 THE WITNESS: So I'm -- if I'm interpreting  
12                 your question right, I don't know specifically -- if  
13                 what you mean is are there indications that are not  
14                 cited on the label, that are just -- there's no  
15                 reference to it, versus are there times when it says do  
16                 not use, or this product is contraindicated, right,  
17                 that's -- there's obviously that would be -- there would  
18                 be a difference. Obviously those labels are different.

19                 So if that's what you mean by "against label."

20                 MR. GIDEON: Q. It's what I mean by  
21                 "against label." Have you not heard that term being  
22                 used to describe that scenario previously?

23                 A. I'm not sure "against label" I've ever -- I'm  
24                 not sure I've ever heard -- again, I think I know what  
25                 that means, but I would probably say where the label



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1 prohibited it or was contraindicated or something like  
2 that.

3 Q. Physicians are free to use medications beyond  
4 the labeled authorized uses, correct?

5 A. So FDA's position, okay, is as you state.

6 Okay. There are other constraints on physicians to use  
7 drugs off-label beyond FDA regulations.

8 Q. There's an explicit provision, 21 U.S.C 396.  
9 Give me that.

10 (Whereupon, Exhibit 1249 was marked for  
11 identification.)

12 MR. GIDEON: Q. This is Exhibit No. 1249.  
13 You are familiar with that --

14 A. Let me just.

15 Q. -- provision of the United States Code, are you  
16 not?

17 A. Let me just take a look at it.

18 Q. Sure.

19 A. What's your question?

20 Q. Doesn't this recite the fact that nothing about  
21 the law pertinent to the Food and Drug Administration  
22 has any impact on the prerogative, the discretion, of a  
23 healthcare practitioner to prescribe or use a drug or  
24 device?

25 A. No, that's not --



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1                   MR. CHALOS: Object to the form.

2                   THE WITNESS: That's not what that states.

3                   MR. GIDEON: Q. What does this state then,  
4 Dr. Kessler?

5                   A. So this applies, as I read this, only to  
6 devices.

7                   Q. Okay. Have you ever researched that issue?

8                   A. I've written extensively on the issue of  
9 off-label promotion, and I implemented the law when I  
10 was FDA commissioner.

11                  But this has nothing -- you see the word drug  
12 here? You handed me that saying that was drugs.

13                  Q. Right.

14                  A. Do you see anything about drugs there?

15                  Q. I've gotten your interpretation.

16                  A. No, no, no. That's not my question. There's  
17 no interpretation. My question is, doesn't say the word  
18 drug there, it says device.

19                  Q. I see. Is the FDA's position that a physician  
20 may use a device for an off-label purpose --

21                  MR. CHALOS: Object to the form.

22                  MR. GIDEON: Q. -- as well as a drug?

23                  A. That's a complicated question.

24                  Q. So there's not a straight answer to it?

25                  A. No. I mean, I've written about this. Let me

1 see if I can give you, in general, the answer.

2 In general, as far as FDA statute is concerned,  
3 I'm not talking about state statutes, I'm not opining on  
4 standard of care or anything else like that. Just  
5 dealing under FDA law. The FDA has generally stated,  
6 and I have stated, that a physician, in his or her  
7 judgment, right, in the best interest of a patient, may  
8 use a drug, right, beyond the intended conditions of  
9 use. That's in the term "drug."

10 A physician may not promote the use, right?  
11 There are limits to what a physician -- if you go back  
12 to U.S. v. Evers, you'll see there are limitations on  
13 what physicians -- and what's off-label promotion, I  
14 mean, by physicians.

15 So in general, again, for an individual  
16 patient, individual physician judgment, subject to, you  
17 know, following -- writing a prescription, following the  
18 rules, best interest of the patients, physician should  
19 use his or her judgment.

20 Q. Okay. Now, you've referred several times to  
21 the fact that a drug manufacturer cannot promote a  
22 purpose that is not within the label, correct?

23 A. So let's do it this way --

24 Q. No, let's just answer the question.

25 A. I am answering your question.



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1 Q. How so?

2 A. Can I --

3 MR. CHALOS: Object to the form.

4 THE WITNESS: So if you look at the statute,  
5 the statute says the intended use. There's two real  
6 requirements. The intend -- you can't promote -- you  
7 cannot have an intended use beyond your application,  
8 okay?

9 No. 2, you have to provide adequate directions  
10 for use that's on the label. So those are the actual  
11 specific requirements.

12 With regard to promotion, you can't have an  
13 intended use --

14 (Reporter clarification.)

15 THE WITNESS: You can't have an intended use.

16 MR. GIDEON: Q. Can or cannot?

17 A. You cannot have an intended use where you go  
18 market this drug, promote this drug, for use beyond the  
19 label.

20 Q. The approved labeling?

21 A. Label.

22 The -- there is -- as you know, there are, in  
23 certain courts, the issue, there's certain First  
24 Amendment cases that relate to the word "promotion."

25 But I think everybody agrees that when it comes

1 to intended use, you can't have an intended use that is  
2 beyond -- again, we're dealing with new drugs here, not  
3 old drugs.

4 Q. All right. Now, is methylprednisolone acetate  
5 a new drug or an old drug?

6 A. So tell me who's -- tell me who's selling it.

7 Q. So the determination of whether something is a  
8 new or old drug depends on who is selling the product?

9 A. Well, so the new drug provisions, right, I  
10 mean, it has to do with who's introducing it into  
11 interstate commerce. That's 505, which is the new drug.

12 So, yes, the introduction into interstate  
13 commerce will trigger the new drug provisions of the  
14 act.

15 Q. Okay.

16 A. So let me answer your question.

17 In the case of Pfizer, right -- you asked me  
18 methylprednisolone acetate, right?

19 Q. Make sure you understand the question --

20 A. I understand this question.

21 Q. Is methylprednisolone acetate a new drug or an  
22 old drug --

23 MR. ARBITBLIT: He's in the middle of his  
24 answer. He's in the middle of his answer. You can't  
25 interrupt him in the middle of an answer. Wait until he

1       finishes.

2            MR. GIDEON: Well, soon some day --

3            MR. ARBITBLIT: Be polite --

4            MR. GIDEON: Soon some day he will answer my  
5 question.

6            MR. ARBITBLIT: He will answer your question.

7 It's not as easy as you think.

8 THE WITNESS: So let me answer your question.

9            MR. GIDEON: Q. Please.

10          A. With regard to Depo-Medrol --

11          Q. No, methylprednisolone acetate is the question.  
12 Not changing the question.

13          MR. ARBITBLIT: You are interrupting. He is  
14 answering your question. If you'll give him a minute,  
15 you'll get your answer.

16          MR. GIDEON: Is that a promise?

17          MR. ARBITBLIT: It is.

18          MR. GIDEON: Okay.

19          THE WITNESS: I -- Depo-Medrol, who's --

20          MR. GIDEON: Q. I didn't ask about  
21 Depo-Medrol.

22          A. Well, could you -- as I asked --

23          MR. ARBITBLIT: If you can't stop yourself from  
24 interrupting, we can just take the lunch break until you  
25 calm down.



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1                   MR. GIDEON: No, I'm not going to need any  
2 time. I just want an answer to the question that's  
3 pending.

4                   MR. ARBITBLIT: Depo-Medrol and  
5 methylprednisolone acetate may be the same thing. If  
6 you let him answer the question, instead of interrupting  
7 him every time he starts to speak, we'll make progress  
8 toward completion. If you can't do that then we'll take  
9 a lunch break now.

10                  MR. GIDEON: Q. I'm going to make sure, so  
11 that it's clear, that the question does not deal  
12 with Fosamax, Depo-Medrol or Bactrim. It deals with  
13 methylprednisolone acetate and only that product.  
14 Now, go ahead.

15                  A. So I'm looking at the label for -- I'm going to  
16 answer your question. Let me -- please let me finish.

17                  Q. Sure.

18                  A. I'm looking at the label for Depo-Medrol, and  
19 the first item in that as the active ingredient is  
20 methylprednisolone acetate. So I'm not sure why you  
21 don't understand that, if I'm talking about Depo-Medrol,  
22 and why you didn't clarify your question, right,  
23 appropriately, right?

24                  So Depo-Medrol is a new drug. There is an NDA  
25 that is in a -- that I assume is in effect that Pfizer

1 holds for Depo-Medrol whose active ingredient is  
2 methylprednisolone acetate. That would be a new drug.  
3 They submitted an application. We'd have to go back and  
4 look at the 1959 record.

5 With regard to methylprednisolone acetate --

6 Q. Which is what I asked you about.

7 A. -- which is also the scientific name of  
8 Depo-Medrol. With regard to that, if it is a product  
9 made by a compounder, okay, as in this case, by NECC,  
10 that methylprednisolone, right, depends on what year and  
11 what court you are asking me about.

12 And up until --

13 Q. What year and what what? Court?

14 A. What year and what court.

15 Up until 1997, I would answer your question  
16 that methylprednisolone acetate made by a compounder was  
17 a new drug subject to the new drug provisions of the  
18 act.

19 The issue then becomes is there enforcement  
20 discretion for methylprednisolone acetate. When  
21 Congress enacted FDAMA in 1997, Congress exempted  
22 compounded drugs for as -- from the new drug provisions,  
23 right?

24 So it then became, in essence, the new drug  
25 provisions were not applicable. 505 was not applicable.



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1 So what would remain applicable was 501(a), right? So  
2 you have, then, if FDAMA is in effect, it's, in essence,  
3 exempt from the new drug provisions.

4 Then you have periods of time where the law is  
5 unclear of whether FDAMA is in effect. So you could  
6 take the position, right, FDA took the position when  
7 western states made FDAMA invalid, right, that the prior  
8 law attached, and that would be a new drug.

9 When Gonzales' opinion came and upheld the  
10 validity of FDAMA, right, then it's exempt from the new  
11 drug. So it depends on what year you're talking about  
12 and what court and what interpretation you put on, which  
13 court opinions govern.

14 Q. Okay. Now Western States reached the Supreme  
15 Court of the United States, didn't it?

16 A. It did.

17 Q. And when Western States reached the Supreme  
18 Court of the United States, the Supreme Court affirmed  
19 the decision striking down the amendments based on first  
20 amendment issues, correct?

21 A. You want to hand me Western States?

22 Q. I'm just asking you, do you know? You gave me  
23 a lecture about the law.

24 Do you remember this reaching the Supreme Court  
25 of the United States?

1 MR. CHALOS: Hang on. Objection.

2 Argumentative.

3 THE WITNESS: So what Western States did --

4 MR. GIDEON: Q. I didn't ask you what it  
5 did. I asked you do you recall that Western States  
6 reached the Supreme Court of the United States?

7 A. You asked me -- that was not your question.

8 Q. It is now.

9 A. Okay.

10 Q. Did Western States reach the Supreme Court of  
11 the United States?

12 MR. ARBITBLIT: Objection. Asked and answered.

13 THE WITNESS: Yes.

14 MR. GIDEON: Q. And the Supreme Court of  
15 the United States is the one and only Supreme Court  
16 in the federal system, correct?

17 A. Yes.

18 Q. All right. Now, after the Supreme Court of the  
19 United States affirmed the lower court decision, were  
20 all methylprednisolone acetates made by compounders  
21 going across state lines now once again new drugs?

22 A. The circuits would split on that question.

23 Q. Massachusetts was not in the Fifth Circuit, was  
24 it?

25 A. No.

1           Q. The Fifth Circuit was the only circuit where a  
2 compounded methylprednisolone acetate was not a new  
3 drug; isn't that correct?

4           A. Go look at -- is it folks -- Franck's? I don't  
5 believe that's in the Fifth Circuit. Maybe I'm wrong.  
6 I'd have to look at a map.

7           I mean, there were multiple court opinions on  
8 Gonzalez and the Fifth Circuit and Ukesse.

9           And I think that certainly certain provisions  
10 of Gonzalez Medical Center were looked at by Franck's,  
11 but we can pull that opinion.

12          Q. All right. As of the time frame 2010 to 2012,  
13 was methylprednisolone acetate made by NECC a new drug?

14          A. It was unclear.

15          Q. And is it unclear to you today whether it was  
16 at that time?

17          MR. CHALOS: Object to the form.

18          THE WITNESS: I'm sorry, was it unclear to  
19 me --

20          MR. GIDEON: Q. Is it unclear to you today  
21 whether methylprednisolone acetate made by NECC was,  
22 in fact, a new drug between 2010 and 2012?

23          A. It's not -- it's not -- I'm sorry. If I  
24 understand your question, it's -- I'm not sure I  
25 understand the difference from the last two questions.



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1                   It was unclear. I think any reading of the  
2 history of this would show that with the circuits split,  
3 right, and with the Supreme Court not answering the  
4 question whether, in fact, the advertising provisions  
5 were severable, with that not being answered, and  
6 without having the 2016 -- I mean, what is it, the new  
7 Drug Quality Act in effect, I think that anyone looking  
8 at this would have to say that it was unclear what law  
9 governed at the time.

10                  FDA did try, for a period of time after  
11 Western States -- I would say, you know, the period  
12 about 2006 to 2008, FDA, you can see, took a position  
13 where it tried, again pretty aggressively, to regulate  
14 these as new drugs, but then you have the split in the  
15 circuits. And then I think there was -- I think it's  
16 fair to say there was confusion.

17                  Q. Is it true that physicians are rarely in the  
18 position to determine whether a drug is safe and  
19 effective? That is the responsibility of the  
20 manufacturer?

21                  MR. CHALOS: Objection to form.

22                  THE WITNESS: So do you want to hand me the  
23 context in which I said that --

24                  MR. GIDEON: Q. Sure.

25                  A. -- I would appreciate it.

1           Q. I'm going to hand you your report in the  
2 Risperdal litigation. You'll take a look at  
3 paragraph 16.

4           This is a report that covers 91 pages, and then  
5 the signature page is on the 92nd. You'll see your name  
6 and a signature date of September 17th, 2012.

7           A. Yes.

8           Q. Okay. Take a look at paragraph 16.

9           A. Yes.

10          Q. And is this not your testimony in 16, quote:  
11 In my opinion, physicians are rarely in the position to  
12 determine whether a drug is safe and effective. That is  
13 the responsibility of a manufacturer, period, end quote?

14          A. Yes, that is my testimony, and let me explain  
15 that.

16          When new drugs are sold, they are extensively  
17 tested and there's volumes and volumes, again, for new  
18 drugs, of data, right? Most physicians -- I don't see  
19 any physicians that I know of -- I mean, physicians  
20 rarely go through and read all that data about safety  
21 and effectiveness to make that judgment.

22          Physicians have other responsibilities, right?  
23 But the reading of the NDA, right, and the judgment of  
24 whether that data supports the risk/benefit equation --  
25 again, we're dealing for new drugs -- whether there's a

1 risk/benefit, if the drug's risks are acceptable in  
2 light of the benefits and whether the drug works, that's  
3 all the data in the NDA, right? And very few physicians  
4 will read an entire NDA. In fact, I've never met anyone  
5 who has read an entire NDA.

6 But that applies to new drugs here, as  
7 Risperdal was here. That's not what you are dealing  
8 with in this case.

9 Q. Is there anything in paragraph 16 that limits  
10 this expression of opinion to new drugs and physicians  
11 not reading the entire NDA?

12 A. The term safe and effective is a term of art,  
13 as you know well, and that's contained in the 505 --  
14 section 505 that applies to new drugs.

15 Q. Uh-huh. Okay.

16 A. That was not an applicable section here.

17 Q. You agree with me that pharmaceutical companies  
18 are prohibited from using third parties to engage in  
19 promotion for which the company itself may not engage?

20 A. That's correct.

21 Q. And that is true of any pharmaceutical company,  
22 isn't it?

23 MR. CHALOS: Object to the form.

24 THE WITNESS: Again, those -- that intended --  
25 those intended use provisions which deal with promotion



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1       that underlies those are all derived from section 505.  
2       And if a drug is exempted from 505, I mean, it's a whole  
3       different regulatory analysis.

4                    MR. GIDEON: Q. Is it your -- do you  
5       intend to offer the testimony in this case that the  
6       methylprednisolone acetate manufactured by NECC was  
7       exempted from section 505 of the Food, Drug and  
8       Cosmetic Act?

9                    What's the answer to that?

10          A. So it was certainly -- it was certainly, from  
11       the period -- the answer is yes. And certainly we know  
12       that there's no dispute that from the period of 1997 to  
13       2002, until Western States, Congress enacted FDAMA. I'm  
14       on record having opposed it.

15                   But there's no question during that period  
16       that --

17          Q. The period '97 to '02?

18          A. Well, before Western States, right? In that  
19       period when FDAMA was in effect, I mean, compounding was  
20       exempt from the -- from 505.

21          Q. Okay.

22          A. Then you have a period, right, after the court  
23       struck down the advertising and promotion issues, you  
24       have this period, maybe 2006 to 2007, 2008, where FDA  
25       tries to reassert authority as a new drug. You see

1 evidence of that.

2 Then beginning in 2000 -- when was -- Gonzalez  
3 was 2006, but Ukeze was 2008. When you have the split  
4 in the circuits, right, then there was just utter  
5 confusion.

6 Q. Well, the time frame I'm interested in is 2010  
7 to 2012. During that time frame, was methylprednisolone  
8 acetate manufactured by NECC and sold in interstate  
9 commerce exempted from section 505 of the Food, Drug and  
10 Cosmetic Act in your opinion?

11 A. I think the answer is it is unclear. I think  
12 that if FDAMA was in effect, as many argued, the answer  
13 would be -- it would not be a new drug. And that was a  
14 position that certainly some people took.

15 Q. And if FDAMA wasn't in effect, a compounded  
16 product was a new drug?

17 A. If FDAMA was not in effect and FDA had  
18 authority, you would -- under the existing act, you  
19 could make an argument that it was a new drug. That was  
20 opposed -- that argument was opposed by -- you know,  
21 there were a lot of difference of opinions. Depending  
22 on where you sat, different groups had different  
23 opinions on -- that's why Congress ultimately  
24 established, you know, a new law.

25 Q. It's true, isn't it, that drug promotion

1       strongly influences prescribing behavior, and that  
2       physicians underestimate the influence of drug promotion  
3       activities?

4                    MR. CHALOS: Object to the form.

5                    THE WITNESS: Sure. You are quoting me. You  
6       are doing a good job.

7                    Let me just put a footnote there. Again,  
8       because the relevance to this case. I mean, there's  
9       still responsibilities on the part of physicians.

10          MR. GIDEON: Q. Is it true, Doctor, that  
11       promotion includes literature?

12          MR. CHALOS: Object to the form.

13          MR. GIDEON: Q. Promotion includes  
14       published literature?

15          MR. CHALOS: Object to the form.

16          THE WITNESS: It -- you know, of course one  
17       could promote a drug -- I mean, companies do promote  
18       drugs by handing out literature.

19          MR. GIDEON: Q. Is it true that promotion  
20       includes conferences?

21          MR. CHALOS: Object to the form.

22          THE WITNESS: Certainly that could -- well, you  
23       are really going to the question of what's labeling,  
24       right?

25          MR. GIDEON: Q. No, I'm just asking

1       questions and hoping I can get, once or twice today,  
2       a direct answer.

3                    MR. CHALOS: Object to the form.

4       Argumentative.

5                    THE WITNESS: Sir --

6                    MR. CHALOS: There's no question.

7                    MR. GIDEON: Q. I'm just reminding you of  
8       something I said a while ago, and that was I really  
9       had a hope that if I asked a succinct question I'd  
10      get a direct answer. I must tell you I'm feeling  
11      disappointed at this stage that it hasn't occurred.

12                  MR. CHALOS: Hang on a second. Objection --

13                  MR. GIDEON: So I'm reminding you to please  
14      answer my questions directly.

15                  MR. CHALOS: I object to the admonition. I'm  
16      sorry you are disappointed, but that's not a proper  
17      question.

18                  There's nothing to answer.

19                  THE WITNESS: Let me put on the record --

20                  MR. GIDEON: No, he's telling you not to speak  
21      anymore.

22                  THE WITNESS: He's not --

23                  Are you instructing me not to speak?

24                  MR. ARBITBLIT: Wait for a question.

25                  MR. CHALOS: I'm suggesting wait for a



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1 question.

2 THE WITNESS: I'll wait for a question.

3 MR. GIDEON: Q. Isn't it true, also, that  
4 any time a pharmaceutical company has reason to know  
5 that the risks of a drug may result in adverse  
6 events, that pharmaceutical company has a  
7 responsibility to inform physicians and healthcare  
8 providers?

9 A. Certainly under 505.

10 MR. ARBITBLIT: Let's take a lunch break.

11 THE WITNESS: Certainly under new drug  
12 provisions.

13 MR. GIDEON: Q. Take a look at  
14 paragraph 326 of your --

15 MR. ARBITBLIT: Counsel, are you reneging on  
16 your offer to take a break whenever we wanted?

17 MR. GIDEON: No, I'm not. But he said under  
18 505, and there's no such qualification on his prior  
19 testimony.

20 Q. Isn't it correct --

21 And then we'll take a break.

22 MR. ARBITBLIT: Okay.

23 MR. GIDEON: Q. -- that paragraph 326 of  
24 your affidavit says precisely what I suggested with  
25 no such qualifications?



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(Whereupon, Exhibit 1250 was marked for identification.)

MR. CHALOS: What exhibit are we looking at here?

MR. GIDEON: He's got it in front of him.

MR. CHALOS: What's the number on that?

**MS. WEEETER:** 1250.

**MR. CHALOS:** 1250?

**MS. WEEETER:** Uh-huh.

MR. ARBITBLIT: And what paragraph?

**MR. GIDEON:** 326.

THE WITNESS: So what you are missing,  
Counselor --

MR. GIDEON: Q. I didn't ask you what I'm missing.

A. I'm answering your question.

Q. Is there any such qualification in paragraph 326 of the affidavit --

A. I'm answering your question.

Q. -- is the question.

MR. CHALOS: Object to the form.

### Argumentative.

THE WITNESS: The -- this has to do with adverse events on the drug's labeling. Those requirements are set out, right, by 505, which applies



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1 to new drugs.

2 MR. GIDEON: Q. Uh-huh. Is there any  
3 reference to section 505 of the Food, Drug and  
4 Cosmetic Act in paragraph 326 --

5 A. No, but I'm --

6 Q. -- of that lengthy statement?

7 A. No, but I'm sure the whole report is predicated  
8 on a 505 drug -- and section 505 is, I'm sure, cited in  
9 this report.

10 MR. ARBITBLIT: And for completeness, the  
11 paragraph just before what you read, Counsel, refers  
12 specifically to the Food, Drug and Cosmetic Act.

13 (Reporter clarification.)

14 MR. ARBITBLIT: Paragraph 325 of the document  
15 from which counsel read refers to the Food, Drug and  
16 Cosmetic Act in its entirety. And so to read 326 in  
17 isolation is incomplete. Pursuant to Rule 106, rule of  
18 completeness, that's appropriate to add.

19 Let's take a lunch break.

20 MR. GIDEON: We're going to take a lunch break.  
21 It's -- it is 12:35 locally.

22 MR. ARBITBLIT: 2:35 Nashville time.

23 MR. GIDEON: 12:35 locally. And we'll take,  
24 what, one hour?

25 MR. ARBITBLIT: If you need it.

1                   MR. GIDEON: I don't need that long if you've  
2 got food coming here.

3                   MR. ARBITBLIT: The food is already out there  
4 on the counter. We can agree that --

5                   MR. GIDEON: Whatever you want to do.

6                   MR. ARBITBLIT: We're off the record, right?

7                   THE REPORTER: No.

8                   MR. GIDEON: Let's go off the record.

9                   THE VIDEOGRAPHER: This is the end of disc  
10 No. 2, volume 1.

11                  We are off the record at 12:33 p.m.

12                  (Recess taken from 12:33 PM to 1:09 PM)

13                  MR. GIDEON: Q. Dr. Kessler, your blotter  
14 with those notes on it, it's been sent off to an  
15 accounting or architectural firm for copying, and  
16 you have said you don't intend to answer questions  
17 until those notes are back, correct?

18                  A. Yes. I would like to have my notes in front of  
19 me as an expert. So I just -- I brought notes. I don't  
20 know the areas that you are going to cover, and  
21 certainly I would like to have the privilege of having  
22 my notes in front of me.

23                  Q. Well --

24                  A. They were taken away and I just would like them  
25 back.



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1           Q. You said a moment ago that if you could find  
2 out what the subject matter is you might change your  
3 mind. And I'll tell you what the subject matter is.  
4 And it's the FDA's 2002 compliance policy guide.

5           Are you comfortable answering questions about  
6 the compliance policy guide without your notes?

7           A. I think so, sir.

8           Q. Good.

9           We need an exhibit number.

10          MR. ARBITBLIT: Do you want to go back on the  
11 video record now?

12          MR. GIDEON: Yes.

13          THE VIDEOGRAPHER: One moment please.

14          This is the beginning of disc No. 3, volume 1.

15          We are back on the record at 1:11 p.m. You may  
16 proceed.

17          (Whereupon, Exhibit 1251 was marked for  
18 identification.)

19          MR. GIDEON: Q. Dr. Kessler, I just handed  
20 you a copy of the Compliance Policy Guides Manual  
21 Section 460.200, which is referred to in a lot of  
22 the papers in this case as the 2002 compliance  
23 policy guide from the FDA.

24          If you look at page 3 of that document there is  
25 a statement that reads as follows: An increasing number



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1 of establishments with retail pharmacy --

2 A. Do me a favor. Show me where, so I'm exactly  
3 reading with you.

4 Q. It is the very first sentence on page 3.

5 A. I see "FDA believes." That's what you --  
6 that's where you're starting. "FDA believes." Thank  
7 you.

8 Q. -- that an increasing number of establishments  
9 with retail pharmacy licenses are engaged in  
10 manufacturing and distributing unapproved new drugs for  
11 human use in a manner clearly outside the traditional  
12 bounds of pharmacy practice and that violates the Act.

13 Do you see that?

14 A. Yes.

15 Q. Okay. What act is this referring to?

16 A. This would be the Federal Food, Drug and  
17 Cosmetic Act enacted in 1938 and amended multiple times  
18 since then.

19 Q. All right. And who were the establishments  
20 with retail pharmacy licenses that were engaged in  
21 manufacturing and distributing unapproved new drugs that  
22 were referred to at page 3 of the CPG?

23 MR. CHALOS: Object to the form.

24 THE WITNESS: You -- I couldn't give you what  
25 was in FDA's mind, exactly, at the time. I don't know

1 exactly what establishments they were talking about in  
2 this. But in general, I think we're talking about  
3 compounding establishments.

4 MR. GIDEON: Q. Was NECC one of those  
5 establishments with a retail pharmacy license  
6 engaged in manufacturing and distributing unapproved  
7 new drugs for human use as of the time of  
8 publication of the compliance policy guide?

9 A. So you didn't read the full sentence.

10 Q. I asked just a question. Was NECC one of those  
11 entities?

12 A. Right. So I don't know specifically. One  
13 would think so. But what you didn't read, right, is the  
14 beginning of the sentence where it says "FDA believes."

15 Q. Uh-huh.

16 A. Right? Whether, in fact, they were engaged in  
17 manufacturing and distributing, I don't know whether FDA  
18 concluded it was NECC.

19 You see at this time, to your question, if my  
20 memory serves me right, that around a similar time in  
21 2002, and I would want my notes for this, that you see  
22 that FDA concluded with the Massachusetts Board of  
23 Pharmacy that NECC was a compounding pharmacy and not  
24 manufacturing. That was specifically discussed around  
25 2002.



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1           And again, I need my notes to look at which  
2 document that is.

3           So at around this time, right, I mean,  
4 specifically with regard to NECC, and I'll give you the  
5 citation as soon as my document -- my notes are back --  
6 I believe FDA concluded, with Massachusetts Board of  
7 Pharmacy, that it was a compounder. So that would not  
8 be consistent with this. So that's the first thing with  
9 regard to NECC.

10          With regard to whether compounders are  
11 manufacturers, again, this says FDA believes. And as I  
12 testified earlier, I think after Western States in 2002,  
13 and this is written thereafter, FDA is trying to  
14 reassert jurisdiction, right?

15          Now, not everybody -- certainly courts did not  
16 agree. The industry did not agree that it was  
17 manufacturing, and FDA, when put to the test to comment  
18 about whether NECC, around this time, concluded that it  
19 was a compounder.

20          So this says what it says, but other documents  
21 would say it was a compound -- NECC was a compounder and  
22 not a manufacturer.

23          Q. Now, did anybody ever provide you with any of  
24 the documents from 2002 and 2003 -- in fact, they're  
25 Penta exhibits -- where FDA describes NECC repeatedly as

1 a manufacturer?

2 A. So --

3 Q. Did they provide you with those documents?

4 MR. CHALOS: Object to form.

5 THE WITNESS: Yes. I've seen 483s.

6 MR. GIDEON: Q. Not a 483. An actual  
7 description by the FDA -- the documents are among  
8 the Penta exhibits -- where the FDA calls NECC a  
9 manufacturer. Have you seen those?

10 MR. ARBITBLIT: Now, Counsel, you are  
11 representing something that's in a document that may or  
12 may not be accurate. If you have something you want to  
13 show him, do so. Otherwise, let him finish his answer.  
14 He was giving you an answer about 483s that he has seen.  
15 You are interrupting him, like, repeatedly, and it's  
16 inappropriate.

17 MR. GIDEON: Oh, my gosh. This is just  
18 ridiculous. You guys would have to recognize -- I think  
19 anybody would -- that his answers have been consistently  
20 nonresponsive, almost from the beginning --

21 MR. ARBITBLIT: I absolutely disagree.

22 MR. GIDEON: Let me finish.

23 -- almost from the beginning. If you ask him  
24 if today is Friday, he gives us a description of the  
25 entire calendar.

1                   It has been nonresponsive all day long. And I  
2 asked him a simple question if anybody had ever given  
3 him the Penta exhibits where the FDA describes NECC as a  
4 manufacturer, and he just starts talking, and then you  
5 defend him. It's ridiculous.

6                   MR. ARBITBLIT: That is so far from a simple  
7 question, Counsel, because it's includes reference to a  
8 document that you haven't shown the witness that may or  
9 may not be consistent with what you are representing.

10                  You don't have the right to represent a  
11 document out of thousands of pages reviewed and pretend  
12 that you are all knowledgeable as to what's in it, or  
13 that he has no right to see it to answer a question.

14                  And he certainly was answering your questions  
15 all day long.

16                  MR. GIDEON: Well, Dr. Kessler has talked a lot  
17 today, but hasn't answered many of my questions. That's  
18 the truth.

19                  MR. ARBITBLIT: Well, that's your vision of the  
20 truth.

21                  MR. GIDEON: I think it will be verified when  
22 an objective party looks as it.

23                  MR. CHALOS: Okay. Is there a question  
24 pending? I've lost track.

25                  MR. GIDEON: He was still talking. I have lost

1 track of what my question was that I asked 22 minutes  
2 ago.

3 MR. ARBITBLIT: Does he have to know whether  
4 the form 483s were part of Penta's exhibits? Is that  
5 what you really want this deposition to be about?

6 He's telling you a responsive answer about a  
7 document that referred to NECC as a manufacturer, and  
8 you want him to tell you whether that was one of Penta's  
9 hundred exhibits? Is that really your idea of a fair  
10 question?

11 MR. GIDEON: Well, let me give you my idea of a  
12 very fair question.

13 Did this witness that you engaged ever see a  
14 Penta exhibit where the FDA described NECC as a  
15 manufacturer? Nobody finds that question difficult to  
16 answer. It's a yes or no.

17 MR. ARBITBLIT: No it's not, because --

18 MR. CHALOS: Object to the form.

19 MR. ARBITBLIT: -- you are asking the witness  
20 to identify which are Penta exhibits out of all the  
21 documents that he's reviewed.

22 And I would advise the witness, if you remember  
23 a document that was a Penta exhibit, you may answer it.  
24 If you remember another document you are not sure if  
25 it's a Penta exhibit, you can advise counsel in your

1 response.

2 MR. GIDEON: Q. Now the question: Did  
3 FDA, in the documents that were made available to  
4 you, specifically describe NECC repeatedly as a  
5 manufacturer?

6 A. So I believe the documents that I -- to answer  
7 that question -- that I would want to look at, that were  
8 made available, the exact documents, are on my notes and  
9 I would like to see that.

10 Q. You know what brought this up is you said that  
11 as you looked at the compliance policy guide, you were  
12 looking at this and you said but -- but the FDA  
13 described NECC as a compounder. What document were you  
14 referring to when you said that?

15 A. So, again, the specific citation is in my  
16 notes, and I'd --

17 Q. The blotter?

18 A. Yeah. I can give you the specific citation.  
19 But from memory, okay, what I remember, which is a  
20 direct answer to your question, okay, is FDA did use the  
21 term -- did use the word manufacturing as it was  
22 inspecting in 2002, right?

23 But in the specific meeting minutes with the  
24 Massachusetts Board of Pharmacy, when asked in this time  
25 period in 2002 whether NECC was a manufacturer or

1 compounder, the agreement was -- the result of FDA's  
2 review, was that NECC was a compounder. I'd be happy to  
3 give you that exhibit as soon as my notes are back.

4 Q. Well, the way we got the opportunity to  
5 continue today's scheduled deposition was I told you I  
6 wanted to ask you about the compliance policy guide --  
7 let me finish -- and you said okay, we can talk about  
8 that before the notes come back. Remember?

9 A. But we're not talking about --

10 MR. CHALOS: Object to the form.

11 Argumentative.

12 THE WITNESS: So -- so, again, I'd be happy to  
13 talk about this in the abstract. If you are talking  
14 about specific documents as they applied to NECC, right,  
15 which you did, I need my notes.

16 MR. GIDEON: Q. I didn't bring it up. I  
17 asked you was NECC one of those establishments with  
18 retail pharmacy licenses that was engaged in  
19 manufacturing and distributing that is referred to  
20 in the first three lines of the compliance policy  
21 guide at page 3. It's a simple question.

22 MR. CHALOS: Object --

23 MR. GIDEON: Q. Was it NECC or not?

24 MR. CHALOS: Objection. Argumentative.

25 THE WITNESS: So I --



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1                   MR. CHALOS: Hang on a second.

2                   Objection. Argumentative. Compound.

3 Objection to form.

4                   THE WITNESS: There's no way that I could know  
5 when the person who wrote this, what was in their mind.

6                   MR. GIDEON: Q. Right.

7                   Now, let's talk about the criteria under the  
8 policy itself that's in front of you.

9                   A. Sure.

10                  Q. Now, this was published after the decision in  
11 Western States, wasn't it?

12                  A. Yes. And before other decisions. Yes.

13                  Q. Well, doesn't it refer to, on page 1 in the  
14 introduction, to the fact that the U.S. Supreme Court  
15 had already acted in Thompson versus Western States?

16                  A. Exactly, sir. But before other court opinions  
17 were at issue.

18                  Q. Right. And getting back to page 3 where it  
19 refers to the policy, was this the published policy of  
20 the Food and Drug Administration?

21                  A. This is a compliance policy guide. That's what  
22 this was.

23                  Q. Yeah. Was it a published policy of the FDA?

24                  A. This was a compliance policy guide, and I'd be  
25 happy to tell you what that means.



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1 Q. Sure. Go ahead.

2 A. Okay.

3 Q. I expected that you would. Was it a published  
4 policy of the FDA or is this something that is simply  
5 collected in a document by some other legal publishing  
6 house?

7 A. So the best way to -- so to establish what this  
8 is, is if you look at the first page, sir, right, in  
9 that black box, right, it tells you what this is.

10 Q. Yes.

11 A. So this reflects FDA's thinking on the topic.  
12 It doesn't confirm any rights or person. It does not  
13 operate to bind FDA to the public, and it doesn't have  
14 the force of law, right? It's not a regulation pursuant  
15 to the APA, right? So it's not a statute or a  
16 regulation. This just -- this gives you what FDA's  
17 thinking is at the time.

18 Q. Okay. Now, if we go to page 3 and we start to  
19 try and make some -- give some meaning to the language  
20 the FDA used, in the second sentence under Policy it  
21 says: However, when the scope and nature of a  
22 pharmacy's activities raise the kinds of concerns --

23 A. I'm sorry, I'm reading -- the second sentence  
24 under Policy is "FDA anticipates." Where are you --

25 Q. Page 3.

1           A. I'm there.

2           Q. Page 3.

3           A. Yes.

4           Q. Second full paragraph --

5           A. Second full paragraph. I'm sorry.

6           Q. -- under Policy --

7           MR. CHALOS: Here are your notes.

8           THE WITNESS: Thank you very much.

9           MR. GIDEON: Q. -- which says: However --

10          A. Yes, sir I got it.

11          Q. -- when the scope and nature of a pharmacy's

12         activities raise the kinds of concerns normally

13         associated with a drug manufacturer --

14          A. Yes.

15          Q. -- and result in significant violations of the

16         new drug, adulteration, or misbranding provisions of the

17         Act, FDA is determined that it should seriously consider

18         enforcement action.

19           Have I read that correctly?

20          A. Exactly.

21          Q. Now, what are the scope and nature of a

22         pharmacy's activities that would raise the kinds of

23         concerns normally associated with a drug manufacturer?

24          A. FDA lists those.

25          Q. Where are those in this document?

1           A. One through nine.

2           Q. Oh, I see. So these items that follow below  
3       that are the kinds of things that would inform the FDA's  
4       decision, correct?

5           A. As well as the context for those.

6           Q. Okay. Now, let's look at No. 1.

7           Was NECC compounding drugs in anticipation of  
8       receiving prescriptions?

9           A. I believe the record shows that they were.

10          Q. Okay. Item No. 1 also refers to quantities.  
11       Except in very limited quantities?

12          A. Yes.

13          Q. There is a section here that refers to  
14       inordinate volume; isn't that correct?

15          A. Yes.

16          Q. Which one is it?

17          A. If you know which one it is, we can save time.  
18       I was reading. There's 1 -- the limited quantities in  
19       1, right? Except in very limited quantities. But  
20       that's in relation to the amount of prescriptions that  
21       they get in afterwards. So that's what the determining  
22       factor is there.

23           So obviously limited quantities, again,  
24       compared to the number of prescriptions they had.

25          Q. Did FDA define the term "inordinate volume"?

1           A. Show me where inordinate volume is. If you can  
2 save me time, I'd be happy --

3           Q. I just asked you if it's defined. Because it's  
4 not defined in this document.

5           MR. CHALOS: Objection to the form.

6           THE WITNESS: So if you look at the '92 policy  
7 that I was involved in, I believe they give examples of  
8 volume in that compliance policy guide.

9           MR. GIDEON: Okay. Let's get No. 19 together.

10           (Whereupon, Exhibit 1252 was marked for  
11 identification.)

12           MR. GIDEON: Q. I'll hand you two letters.  
13 One is Exhibit 1252, it's two letters. It's dated  
14 February 18th, 2003 and March 17th, 2003.

15           A. Sure.

16           Q. These are letters to Susan Liner Recall  
17 Coordinator at the Food and Drug Administration. They,  
18 together, are Exhibit 1252.

19           A. Right. And if I could just agree that when I  
20 got my notes -- get back, if someone could pull S0486 in  
21 response to a previous question.

22           Q. I want you to look at these two documents.  
23 First thing I want you to do after you look at them is,  
24 have you seen them before?

25           A. Right.



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1 Q. What are you looking at?

2 A. I'm looking to be able to answer your question.  
3 I want to check my memory.

4 Q. You need to identify for us what's on your  
5 computer screen.

6 A. These are just -- this is my expert report, and  
7 the documents cited in that report, and I just want to  
8 double-check something.

9 Q. Just tell us the paragraph that you are looking  
10 at.

11 A. The paragraph of my -- that I am looking at --

12 Q. Whatever is on the screen, tell us what you are  
13 looking at.

14 A. So I'm looking at -- right now I'm looking at  
15 the responses of NECC to Liner. I'm just looking to see  
16 whether I have this document. Whether I've looked at  
17 this document.

18 Q. Are you looking at a list of documents or are  
19 you looking at any of the content of your reports?

20 A. I'm looking at the content of my reports.

21 Q. Okay. So what are the paragraph numbers?

22 A. Right now, I'm into the schedules.

23 Q. Schedules or paragraphs?

24 A. Schedules don't have paragraphs, sir.

25 Q. Okay. Well, I asked you a paragraph number and



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1 you said yes, I'll answer that. Are you looking at a  
2 paragraph of your report or a schedule?

3 MR. ARBITBLIT: Object to form.

4 THE WITNESS: Am I looking -- I'm not looking  
5 at a paragraph. Right now I'm looking at an actual  
6 document.

7 MR. GIDEON: Q. We know that, Doctor, but  
8 what part of your report are you looking at for the  
9 last time?

10 A. I'm looking at -- so I have, in front of me, an  
11 OCR of all the documents, both in my schedules and my  
12 appendices and my report. So I have an OCR of some  
13 2,000 pages. And -- that I have looked at.

14 That I want to just finish one other thing if I  
15 may.

16 Q. We'll make that OCR --

17 A. It's on the hard drive, sir.

18 Q. Well, we'll have to print out the hard drive  
19 that you offered to me earlier.

20 A. That's 2,000 pages.

21 Q. Correct. But with respect to the OCR that  
22 you're referring to, we will make that Exhibit 1253.

23 MR. CHALOS: We'll provide that electronically.  
24 It's 2600 pages.

25



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(Whereupon, Exhibit 1253 was marked for identification.)

THE WITNESS: Hold on one second. I have to get another thumb drive which is the FOI documents.

I have the FOI documents on another thumb drive, but I have to find it here. For some reason my folder is empty here, but I have to check.

I don't see this document in my schedules or appendices, but I have to check one other file. I don't recall off the top of my head certainly with regard to the first one. Let me just see the second one.

MR. GIDEON: Q. The two letters are from the same lawyer to the same person at FDA involving the same manufacturer, NECC.

A. Right.

**MR. ARBITBLIT:** Object to the preamble.

MR. GIDEON: Just trying to facilitate his review of the document.

MR. ARBITBLIT: You're including a term of  
art --

MR. GIDEON: Trying to be helpful.

MR. ARBITBLIT: -- in your facilitating.

THE WITNESS: So I am aware of the recall and some of the communication. I'd want to check and make sure that I've seen this letter.



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1                   MR. GIDEON: Q. Well, that was the  
2 question. I handed them to you and wanted to know  
3 if you had seen those before. Do you have a memory  
4 of seeing those letters before?

5                   A. I have a memory of the back and forth on the  
6 recall, but I don't recall exactly this letter.

7                   Q. Okay. Well, you can see here, these are from  
8 the Board of Registration and Pharmacy, documents 16762  
9 to 16764, and 16816 to 16817. This reflects volume of  
10 product being recalled at the behest of the FDA and the  
11 Board of Registration and Pharmacy, doesn't it?

12                  A. Yes.

13                  MR. ARBITBLIT: Object to form.

14                  MR. GIDEON: Q. And the volume shown on  
15 the two letters is a volume that is inordinate for a  
16 retail pharmacy, is it not?

17                  MR. CHALOS: Object to the form.

18                  THE WITNESS: So the statute -- what the  
19 statute says -- let me finish, sir.

20                  What the compliance policy guide says, okay, to  
21 the provision that we've talked about on limited use,  
22 the issue is it would be -- the limited use, okay,  
23 depends on the number of prescriptions that the company  
24 had. So what the compliance policy guide is very clear  
25 about, compounding drugs in anticipation, except in very

1 limited instances --

2 MR. GIDEON: Q. No, it says quantities.

3 A. Very limited quantities in relation to the  
4 amount of drugs compounded after receiving valid  
5 prescriptions.

6 Q. Okay.

7 A. So the concept here is it is -- if you have --  
8 this all determines, this all hangs on the central  
9 premise of whether there were prescriptions here.

10 Q. And did you see, in any of the documents you  
11 looked at, whether FDA and the Board of Registration and  
12 Pharmacy even checked to see if there were prescriptions  
13 for any of those products that were recalled?

14 A. So, again, in general, I did not see that.  
15 Okay? I didn't see, in 2002 -- let me correct that.

16 Can I just get S0486, please? Could someone  
17 help pull that? That's a Massachusetts Board of  
18 Pharmacy document.

19 I did not see, again -- again, generally that  
20 would be the state medical board that would be looking  
21 at prescriptions. I didn't see that.

22 Thanks for the help, Don.

23 Q. You didn't see whether the FDA or the  
24 Massachusetts Board of Registration and Pharmacy even  
25 checked to see if those recalled drugs were covered by a

1       prescription, correct?

2           A. Exactly. I did not see that.

3                   Let me add, you -- just so it's on the record.

4       You asked me -- and I apologize, but you asked me  
5       earlier about whether NECC was viewed as a manufacturer,  
6       and I told you that it was viewed by a compounder.

7                   And on page S0486, right, an FDA document  
8       between Kristina Joyce and the central file, it says a  
9       discussion was held to decide if NECC should be  
10      considered a manufacturer or compounder. It says it was  
11      decided that the current findings supported a  
12      compounding role. And this is February 2003.

13                  So that was the way FDA viewed, certainly at  
14      that point in time, based on that document.

15                  Q. Okay. Well, we have two letters before us,  
16      though, don't we? We've got one dated February 18th,  
17      2003, and one dated March 17th, 2003, correct?

18                  A. Yes.

19                  Q. Let's take them in chronological order.

20                  A. Yes.

21                  Q. If you will look at the second page of the  
22      February 18th, 2003 letter to Susan Liner --

23                  A. Right.

24                  Q. -- it has a table that was prepared by the  
25      lawyer for NECC reflecting the volume compounded and the

1       volume distributed, correct?

2           A. Yes.

3           Q. All right. And I suspect that there will be  
4       disagreements about the numbers, but if we estimate,  
5       based on the numbers shown on that page, we certainly  
6       can reach the conclusion that thousands of vials were  
7       distributed of methylprednisolone, 80-milligram per  
8       milliliter, Preservative-free suspension, as shown on  
9       page 2 of that exhibit, correct?

10          A. Certainly if you look at the volume distributed  
11       and you add up the third column, you would get to  
12       several thousand.

13          Q. All right.

14          A. You would get into the thousands.

15          Q. Let's go back. Let's go back and take a look  
16       at page 3 of the compliance policy guide.

17          A. Yes.

18          Q. At the top of the page, FDA offers this  
19       example. Quote: For example, some firms receive and  
20       use large quantities of --

21          A. Just show me exactly where you are reading it.  
22       I'm on page 3 looking at the first sentence.

23          Q. I'll count the lines for you.

24          A. Thank you very much.

25          Q. Line 10. "For example." After "retail

1       pharmacies" there's a period.

2           A. I see a sentence that says "Moreover."

3           Q. Then there is, "For example."

4           A. I see "Moreover," then, "Pharmacies engaged" is  
5 the next sentence. Am I misreading -- you are in the  
6 first existing paragraph on page 3?

7           Q. Yes. Ten lines down.

8           A. It's the sentence before "Moreover." I see it.  
9 "For example, some firms receive."

10          Q. Here. I'll read it to you: For example, some  
11 firms receive and use large quantities of bulk drug  
12 substances to manufacture large quantities of unapproved  
13 drug products in advance of receiving a valid  
14 prescription for them. Moreover, some firms sell to  
15 physicians and patients with whom they have only a  
16 remote professional relationship. Pharmacies engaged in  
17 activities analogous to manufacturing and distributing  
18 drugs for human use may be held to the same provisions  
19 of the Act as manufacturers, end quote.

20          I've read that correctly, haven't I?

21          A. Exactly, sir.

22          Q. Isn't what's shown on page 2 of the February  
23 18th letter a large quantity of methylprednisolone  
24 acetate?

25          A. It -- volume is what it is.



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1           Q. Right. Is it a large quantity, is the  
2 question.

3           MR. CHALOS: Object to form.

4           THE WITNESS: Can I -- let me find -- let me  
5 answer that question precisely with some standard. Hold  
6 on a second.

7           So if you look and can do this --

8           MR. GIDEON: Q. Show us what you are  
9 looking at.

10          A. If you want -- again, if you want the judgment  
11 of what's large and what's not large, because it's not  
12 defined here. But if you look at, in my report, S0337.

13          So I mean, in the earlier compliance policy  
14 guide when FDA was talking about large, it used an  
15 example of 300,000 doses, units of albuterol for 6,000  
16 patients. Those were the numbers that I've seen to just  
17 have a standard. So we know that that is -- that would  
18 be large.

19          Q. 300,000 units for 6,000 patients?

20          A. Yeah. They used an example, has issued warning  
21 letters that they're clearly manufacturing. So we know  
22 that that's an example, right, that I can point to  
23 something concrete.

24          Q. Is that the only example offered in the earlier  
25 compliance policy guide?

1           A. Only one I've seen, sir. I mean, it's the  
2 only -- when you look for what's large, what's not  
3 large, right? But that's absolute numbers, you  
4 understand?

5           The real issue, when you want to know -- it's  
6 not just whether it's large, it's -- is it large  
7 compared to the number of prescriptions it had. That's  
8 the key determiner.

9           Q. Okay. Well, would 10,412 vials, in your  
10 opinion, have been a large quantity of compounded  
11 product which would be more analogous to manufacturing?

12          A. If they had 10,000 prescriptions, then that's  
13 not an issue.

14          Q. Correct. But if they don't have 10,412  
15 scripts, would 10,412 vials of methylprednisolone,  
16 80-milligram per milliliter single-use vials be a large  
17 quantity?

18          MR. CHALOS: Hang on a second. Objection.  
19 Form. Incomplete hypothetical.

20          THE WITNESS: So if you have -- if you don't  
21 have prescriptions, if you are not doing this with  
22 regard to -- you don't have prescriptions and you are  
23 not going to get those prescriptions, right, there's  
24 something that's wrong.

25          MR. GIDEON: Q. Is it -- is 10,412 vials a

1 large quantity analogous to manufacturing?

2 MR. CHALOS: Object to the form.

3 THE WITNESS: I can tell you that 10,000 is  
4 large. With regard to whether it's a manufacturer, it  
5 doesn't meet the 300,000 test here that we've -- not  
6 that it's a test, but that example. So we know it  
7 doesn't meet that.

8 But the issue, for me, as a -- whether it's  
9 manufacturing or compounding, the real central premise  
10 is is this patient-specific prescriptions. That's  
11 what's key here. That's what's missing in this whole  
12 thing. That's what your client and NECC were engaged in  
13 this scheme to do this without.

14 Q. Okay. Tell me this: As you look through these  
15 other factors in the compliance policy guide it says, on  
16 item No. 3: Compounding finished drugs from bulk active  
17 ingredients that are not components of FDA-approved  
18 drugs without an FDA sanctioned investigational new drug  
19 application in accordance with 21 U.S.C. 355 and 21 CFR  
20 312.

21 Do you see that?

22 A. I do, sir.

23 Q. Did NECC compound drugs from bulk active  
24 ingredients that were not components of FDA-approved  
25 drugs without an FDA sanctioned investigational new drug



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1 application?

2 A. So I did not see any IND, so it didn't have  
3 that. Okay. I have not been privy to where the bulk  
4 drug came from, right? I've not seen the drug master  
5 file that would -- to know where that bulk drug came  
6 from.

7 Q. Okay. Can you answer the question?

8 A. Unless I knew -- I would need to see the drug  
9 master file of where that drug came from to know whether  
10 that was an approved drug. I just don't -- I've not  
11 seen that. No one has provided me with that -- I've not  
12 seen where the bulk drug comes from and the status of  
13 that bulk drug.

14 Q. Okay. Item No. 6 refers to: Using commercial  
15 scale manufacturing or testing equipment for compounding  
16 drug products.

17 Was NECC using commercial scale manufacturing  
18 or testing equipment?

19 A. So I believe FDA, at one point, asked that  
20 question specifically as part of the 483. It was one of  
21 the questions that was asked. And I'd have to pull up  
22 that document to see whether, in fact, what -- NECC's  
23 response. I don't see any determination when I -- from  
24 just sitting here, that FDA concluded that it was,  
25 right?

1                   So I mean, again, I would want to see the 483s.  
2 I think there's a direct question on that matter.

3                   Q. In the space of two months, can a retail  
4 pharmacy make 10,412 vials of methylprednisolone acetate  
5 without commercial scale manufacturing equipment?

6                   MR. CHALOS: Object to the form.

7                   THE WITNESS: Again, let me let somebody  
8 else -- we'd have to look and see what that definition  
9 is. I'm not aware that there was -- I'm not aware what  
10 FDA or -- what the equipment was, nor what FDA -- what  
11 the equipment was, nor what FDA concluded.

12                  So you have to show me the equipment that was  
13 in use. Is it possible in two months to make 10,000  
14 vials --

15                  MR. GIDEON: Q. Of MPA.

16                  A. -- of MPA. From my experience and sitting in  
17 pharmacies, I'm just trying to think going back to my  
18 days of doing products. So I would guess I could  
19 probably do a thousand unit doses of compounded product,  
20 I mean, when I sat there in the pharmacy.

21                  Q. When was this?

22                  A. This was when I was -- I had the  
23 responsibility, you know --

24                  Q. When?

25                  A. This was back in the 1980s when I was running

1 the hospital. And when we would have strikes, when  
2 there was strikes in New York, I would actually go down  
3 and work in the pharmacy.

4 Q. Did you have a pharmacy license in New York?

5 A. I was medical -- I was licensed as a physician.

6 Q. No. My question was, did you have a pharmacy  
7 license in New York?

8 A. I had a license as a physician. And under  
9 New York law, I was able to be able to work in the  
10 hospital pharmacy during a strike in an emergency to  
11 save the lives of patients.

12 Q. Okay. And you were compounding thousands of  
13 vials of methylprednisolone acetate?

14 A. No, I didn't say that. I'm just trying to  
15 anticipate. I was sitting there unit dosing certain  
16 things under the supervision of pharmacists, okay? As a  
17 physician, and I was just trying to understand, you  
18 know, trying to prepare unit dose medicines, which is,  
19 in essence, a form of compounding and how many I could  
20 have done that day.

21 Again, let others testify exactly what is  
22 feasible and not. I did not see the equipment, nor did  
23 I see FDA making a determination on that equipment.

24 Q. Okay.

25 A. Again, if someone could help me, I can search

1       in a minute, but I don't want to take your time of what  
2       the -- what's in the 483 on the answer to that question.

3           Q. Which 483 are you referring to, the one from  
4       2002 to 2003 or the one that's post-outbreak?

5           A. No. I'm talking about earlier on, there were,  
6       I believe there were questions that were asked that went  
7       to these kinds of -- and it may be in the EIR or in  
8       other FDA documents. I did see some reference to these  
9       things early on.

10          Q. In this time frame that we are talking about,  
11       which is 2002, 2003, the time frame set by the letters  
12       in front of you --

13          A. Yes.

14          Q. -- was NECC compounding drug products that were  
15       commercially available in the marketplace, or were  
16       essentially copies of commercially available  
17       FDA-approved drug products?

18           This is item No. 8 on page 4 of the compliance  
19       policy guide.

20          A. It would depend on your interpretation. I  
21       think there's different interpretations one could give  
22       to that.

23          Q. What's your answer? What's your  
24       interpretation? The witness' interpretation?

25           Was NECC compounding drug products commercially



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1 available in the marketplace or that are essentially  
2 copies of commercially available FDA-approved drug  
3 products, period?

4 A. It would depend on your interpretation whether  
5 preservative free is essentially the same or not.

6 Q. What do you think?

7 A. Well, you know, I've -- the FDA does give a  
8 definition of essentially the same. I'd have to pull  
9 that definition. I think there's an -- I mean, there  
10 are arguments both ways, would be my opinion.

11 Q. Arguments both ways. Okay.

12 A. If you take the view that the preservative free  
13 wasn't necessary, and that there was approved drug as,  
14 you know, Culclasure and others were using don't care,  
15 then it's the same as a copy. If you're taking the  
16 position that preservative free is something different,  
17 then it's not a copy.

18 Q. Well, was -- was Depo-Medrol preservative free  
19 or not?

20 MR. CHALOS: Object to form.

21 THE WITNESS: We already went through that.

22 MR. GIDEON: Q. It wasn't?

23 A. It had benzyl alcohol.

24 Q. So methylprednisolone acetate is indisputably  
25 not a copy of Depo-Medrol, is it?



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1                   MR. CHALOS: Object to the form.

2                   THE WITNESS: The active agent -- I mean,  
3 again, this is complicated law and I've been in these  
4 situations, okay? The active agent, okay, I mean --

5                   MR. GIDEON: Q. The methylprednisolone  
6 acetate?

7                   A. Which is in Depo-Medrol -- that's what your  
8 active agent -- you have inactive agents and you have  
9 preservative.

10                  But, you know, I think one could argue that it  
11 is a copy of something that is on the market. And I  
12 think if you want to emphasize that it was preservative  
13 free, then you would conclude that it is not. So that's  
14 why I think there could be differences of  
15 interpretation.

16                  Q. Okay. Well, if, in fact, methylprednisolone  
17 acetate without benzyl alcohol, which is not a duplicate  
18 of Depo-Medrol, was being made by NECC, their  
19 methylprednisolone acetate is unequivocally a new drug,  
20 then, isn't it?

21                  MR. ARBITBLIT: Object to form.

22                  THE WITNESS: Sorry, let me understand your  
23 question. Is if -- not if FDAMA is in effect.

24                  MR. GIDEON: Q. FDAMA struck down --  
25 struck down by the Supreme Court of the

1       United States.

2           A. No, sir. That's incorrect. Okay? So what we  
3 know is the advertising provisions are struck down,  
4 right? The Supreme Court did not decide, and you can  
5 read the opinion, you know, that it did not strike down  
6 FDAMA. It didn't decide that. That's what led to the  
7 confusion and the circuits split whether the compounding  
8 FDAMA was valid or not valid.

9           Q. Okay. Well, then let's try and focus on the  
10 FDA's announced compliance policy guide --

11          A. Sure.

12          Q. -- and see if we can make some sense of this  
13 with respect to NECC.

14           With me?

15          A. Sure.

16          Q. All right. When you look at 10,412 vials being  
17 recalled as shown on page 2 of the February 18th letter  
18 to Susan Liner at the FDA, okay? Are you still with me?

19          A. Yeah, I'm with you but I'm just trying to --

20          Q. And then you look at pages 1 and 2 of the March  
21 17th letter --

22          A. Yes, sir.

23          Q. -- have you looked at that?

24          A. Yeah.

25          Q. And the last sentence on the final full



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1 paragraph on page 1 of the March 17th letter begins as  
2 follows: The states into which those lots of  
3 betamethasone were shipped include, and then there is a  
4 list of -- it's either 27 or 28 states.

5 A. Yes.

6 Q. It runs from Arizona to Wisconsin.

7 A. Yes.

8 Q. Now, when you put these two together, doesn't  
9 this show to you that NECC, at the time, was making a  
10 large quantity of preservative-free drug products  
11 analogous to manufacturing?

12 MR. CHALOS: Object to the form.

13 THE WITNESS: If you're preservative free and  
14 you are emphasizing preservative free, that's not a  
15 compound -- that's not a drug that's commercially  
16 available, right?

17 If it's not a drug that's commercially  
18 available, okay, you have to meet -- you're either a  
19 compounder or a manufacturer. We know -- there's no  
20 doubt that on February 24th, 2003, right, Massachusetts  
21 Board of Pharmacy and FDA concluded, right, that it was  
22 decided the current findings supported a compounding  
23 role for NECC. That was FDA. That's what we know in  
24 this time period.

25 So on the basis of what everything FDA had,

1 which was the compliance policy guide, it had all the  
2 facts, these letters, right, certainly by -- within  
3 that -- you know, a 12-month period, the FDA concluded,  
4 through this whole episode, that it was a compounder.

5 MR. GIDEON: Q. If you're distributing  
6 something that is not commercially available, you  
7 are either a compounder or you are a manufacturer,  
8 correct?

9 MR. CHALOS: Object to the form. Object to the  
10 premise of the questions. Misstating the testimony.

11 THE WITNESS: Are you distributing it with  
12 regard to prescriptions? Do you have patient-specific  
13 prescriptions or any anticipation of patient --

14 MR. GIDEON: Q. No. You have no patient  
15 prescriptions. You are distributing bulk volumes.  
16 It is not commercially available. Are you a  
17 compounder or a manufacturer?

18 MR. ARBITBLIT: Object to form. Incomplete  
19 hypothetical.

20 THE WITNESS: Okay. My view would be is if you  
21 are -- you can't be a compounder.

22 MR. GIDEON: Q. Cannot?

23 A. You cannot be a compounder, okay? If you are  
24 distributing drugs and you get no prescriptions in,  
25 right, and it's not in anticipation of prescriptions,

1 then you should not be a compounder.

2 The essential definition of compounding has to  
3 have -- I mean, I assume it's on the first page of the  
4 compliance policy guide. The first beginning. It's all  
5 about patient-specific prescriptions.

6 Q. Okay. Well, what's the definition of a  
7 manufacturer?

8 MR. CHALOS: Object to the form.

9 THE WITNESS: Under what purposes? For what  
10 purposes?

11 MR. GIDEON: Q. What is the definition of  
12 a manufacturer to making large volumes of drugs?

13 MR. CHALOS: Object to the form.

14 MR. GIDEON: Q. What are the criteria that  
15 would allow any reasonable person to say they are  
16 manufacturing?

17 MR. CHALOS: Object to the form.

18 THE WITNESS: So, I mean, our entire -- our  
19 entire legitimate drug supply, I mean, in this country  
20 is, you know, Pfizer and Abbott. Those are  
21 manufacturers. They don't need physician --  
22 patient-specific practices. They are introducing a drug  
23 in interstate commerce, right, for sale, and they are  
24 subject to 505, right? They are clearly manufacturers.

25 MR. GIDEON: Q. Okay. I know that Pfizer

1       is a manufacturer and I know Abbott is a  
2       manufacturer. What I want you to do, though, is  
3       tell us what is the definition of a manufacturer.  
4       Don't just tell me a company name. That's not  
5       helpful. Tell me what the definition is.

6                    MR. CHALOS: Object to the form.

7                    THE WITNESS: So a -- under which law?

8                    MR. GIDEON: Q. The --

9                    A. Under FDAMA or not under FDAMA?

10                  Q. The Food, Drug and Cosmetic Act of 1938, as  
11       amended, up to and including but not including the 1997  
12       FDAMA.

13                  A. Not including --

14                  Q. Not including FDAMA.

15                  MR. CHALOS: Object to the form.

16                  THE WITNESS: So if you wanted to do that,  
17       that's what I wrote specifically in the -- that's what  
18       we wrote specifically in the 1992, 1994 compliance  
19       policy guide.

20                  MR. GIDEON: Q. What is it?

21                  A. Okay. And it gave certain -- that gave certain  
22       criteria, okay, that if you were engaged in -- they were  
23       not -- they were, I don't know, seven, eight, nine  
24       criteria that were part of that policy guide whereby  
25       even if you were a retail pharmacy, the agency would not

1 grant enforcement discretion.

2 Q. Okay. I'm going to ask again. What is the  
3 definition of a manufacturer? Please give me some  
4 substance to your answer instead of just telling me  
5 about things I might find somewhere else at another  
6 time.

7 MR. CHALOS: Object to the form. Object to the  
8 commentary.

9 MR. GIDEON: Q. And if you honestly can't  
10 answer --

11 A. No, I --

12 Q. If you can't answer the question, just say so.

13 A. I can answer this very -- I mean -- and I think  
14 I just did, right?

15 Q. No, you didn't.

16 A. Yes, I did. Well, I think I did.

17 If you turn to page S0338 in my report, just  
18 turn there.

19 Q. Okay. Why don't you read it to us.

20 A. Okay.

21 Q. What is the definition of a manufacturer?

22 A. So FDA -- this is where FDA -- FDA may, in the  
23 exercise of its enforcement discretion, initiate federal  
24 enforcement actions against entities, okay, and  
25 responsible persons when the scope and nature of a



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1       pharmacy's activity raises the kinds of concerns  
2       normally associated with a manufacturer, and that  
3       results in significant violations of the new drug  
4       adulteration or disbanding provision of the Act. In  
5       determining whether to initiate such actions, the agency  
6       will consider whether the pharmacy engages in any of the  
7       following acts, and then lists nine things. And then  
8       says the foregoing list of factors is not intended to be  
9       exhaustive, and any other factors may be appropriate for  
10      consideration in a particular case.

11           What is -- I mean, anyone who introduces,  
12       right, a drug in the -- in interstate commerce, right,  
13       is subject, I mean, for the purposes of selling that  
14       drug is a manufacturer, unless FDA either gave it an  
15       exception, as traditional compounding, right, or FDAMA,  
16       right, basically gave it an exemption from the new drug  
17       acts and they were allowed to introduce stuff in  
18       interstate commerce.

19           Q. Did FDA offer a definition of manufacturer in  
20       any source other than what you just read to us, which is  
21       largely duplicated in the compliance policy guide, isn't  
22       it?

23           A. Well, it was in earlier compliance policy  
24       guide.

25           Q. But the nine factors that you pointed to in the

1 document in front of you are essentially the same nine  
2 factors in the 2002 compliance policy guide; isn't that  
3 correct?

4 MR. CHALOS: Object to the form.

5 THE WITNESS: Right. Yes. We can search  
6 through the regs, and happy to do that, and see where  
7 the word manufacturer -- I use the word manufacturer  
8 as -- generally as a drug sponsor, a drug manufacturer,  
9 the holder of an NDA is a drug manufacturer. I've used  
10 those terms. Those are all people who introduce things  
11 in interstate commerce subject to 505.

12 Compound, we're dealing with this gray area of  
13 retail pharmacy and when is retail pharmacy allowed to  
14 introduce things in interstate commerce and when do they  
15 cross the line. That's the issue.

16 MR. GIDEON: Q. Well, of course. Now,  
17 look at the second letter.

18 A. This is the May 17th?

19 Q. March --

20 A. March. Sorry.

21 Q. March 17th.

22 The lawyer for NECC is admitting to the FDA  
23 that NECC has recalled product from 26 or 27 states,  
24 correct?

25 A. That was -- is part of the FDA inspection, I

1 believe. Yes.

2 Q. And it is crystal clear, then, not subject to  
3 dispute or argument, that NECC is selling product in  
4 interstate commerce in at least half the states in the  
5 country, correct?

6 A. That's correct.

7 Q. Okay. Likewise, it's clear from the earlier  
8 letter that at least 10,000-plus vials were recalled,  
9 right?

10 A. Right.

11 Q. So you have volume, you have clear-cut evidence  
12 of interstate commerce by NECC. Is there any reflection  
13 in any of the materials you have made available to you  
14 that FDA asked for, or NECC represented, that they had a  
15 new drug application approval for the product they were  
16 selling?

17 MR. CHALOS: Objection to form.

18 THE WITNESS: There is no --

19 MR. CHALOS: Hang on a second.

20 Objection to form. Misstates the substance of  
21 these letters.

22 THE WITNESS: The question is independent of  
23 the letters, correct?

24 MR. GIDEON: Q. It is. Has nothing to do  
25 with the letters.

1                   Is there any indication that FDA asked, or NECC  
2 represented, that they were compounding from bulk active  
3 ingredients that are, in fact, components of  
4 FDA-approved drugs?

5                   A. You just changed your question. You first  
6 asked me is there any evidence, if I'm correct, whether  
7 NECC had a new drug application in effect, right?

8                   I am not aware, and I'm sure FDA was fully  
9 aware, that there was no new drug application because  
10 NECC was saying it was a compounder. NECC is saying  
11 we're doing all this subject to patient-specific  
12 prescriptions. That's its representations at the time.

13                  Q. Oh, that's what NECC represented to the FDA  
14 that they were doing all this subject to  
15 patient-specific prescriptions. Where is that in the  
16 documents that have been made available to you?

17                  A. So if you go to BOP00934, I believe there's  
18 that statement back in around the 2002 area.

19                  Q. Okay.

20                  A. And also if you look at, I believe, S0496. But  
21 again --

22                  Q. S0496?

23                  A. I have it written down as S496, but it must  
24 be -- I think it's S0496, but I'd have to double-check.

25                  Q. Was FDA entitled to rely upon the



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1 representations by NECC?

2 MR. ARBITBLIT: Object to form.

3 THE WITNESS: I see no statutory prohibition  
4 against that.

5 MR. GIDEON: Q. I asked you a question.

6 In terms of enforcement, was FDA entitled to rely  
7 upon the representation by NECC that all of these  
8 drugs, you say, were covered by patient-specific  
9 prescriptions?

10 A. I didn't say these --

11 MR. ARBITBLIT: Object to form. Argumentative.

12 THE WITNESS: -- these drugs were covered by  
13 patient prescriptions. Please understand, there was a  
14 scheme here, right?

15 MR. GIDEON: Q. In 2002 is the time frame  
16 we're talking about.

17 A. Well --

18 Q. That's what we're talking about.

19 A. So I don't see the data from 2002. The data  
20 that I -- sorry. Let me be very clear.

21 There is a statement, okay, in direct  
22 questions, I mean, that NECC represents in 2002 that  
23 they dispense approved product in bulk for  
24 administration to individual patients pursuant to  
25 receipt of a valid prescription from a prescriber.



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1           Q. And that's why I asked you, and we've spent ten  
2 minutes on this, was FDA entitled to rely upon that  
3 representation by NECC? It's a simple question.

4           A. It's not.

5           MR. CHALOS: Hang on.

6           Objection.

7           THE WITNESS: It's naive, sir.

8           MR. CHALOS: Objection. Argumentative.

9           THE WITNESS: With all due respect, it can't be  
10 simple. What do you mean "entitled" -- you are a  
11 sophisticated lawyer. What do you mean "entitled" by?

12           MR. GIDEON: Q. You tell me. You used to  
13 be commissioner of the FDA. Were the folks on the  
14 ground talking to NECC there as employees of the  
15 United States of America, were they entitled to  
16 accept the representation of a compounder that these  
17 products are being dispensed based on individual  
18 patient-specific prescriptions? Were they  
19 entitled --

20           A. Entitled under what?

21           Q. I don't know. Was it --

22           A. You are asking the question, so let's just not  
23 make this in the abstract --

24           Q. You tell me from an FDA standpoint, were the  
25 employees entitled to rely upon the representations by



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1 the compounding?

2 A. Entitled?

3 Q. Yeah --

4 MR. CHALOS: Objection.

5 THE WITNESS: Entitled is a matter of law.

6 MR. GIDEON: Q. Well, let's start there.

7 A. Entitled is a matter of law. I see nothing in  
8 the statute that says you can't rely on a statement.

9 Q. You can or cannot?

10 A. You cannot. I see nothing that says, in the  
11 statute, if you make a statement to me, I mean, in  
12 writing, which is subject to -- what is it --  
13 18 U.S.C. 1001, that's a statement to a federal  
14 official.

15 Q. Right.

16 A. Federal officials are allowed to rely on  
17 statements made to them. Of course you are.

18 Q. Okay.

19 A. Let me finish the answer.

20 At the same time as you see in the documents,  
21 right, there was a -- there was a decision, right, that  
22 at that time, that they -- that NECC was engaged in a  
23 compounding role. And therefore, the decision was made  
24 to let the state of Massachusetts take the lead.

25 In fact, you know, most of the time, I have



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1 never, as FDA commissioner, gone into the issue of the  
2 appropriateness of prescriptions. That's usually a  
3 state matter.

4 Q. You have or have not?

5 A. I have not. Right? Most of the time the issue  
6 of prescribing and whether something is a valid  
7 prescription, right, I mean, that's usually a state  
8 matter.

9 Q. And it does differ from state to state.

10 MR. CHALOS: Objection.

11 THE WITNESS: Whether a valid -- yeah, I  
12 mean --

13 MR. GIDEON: Q. Listen to me. State law  
14 differs with respect to what is and isn't a valid  
15 prescription from state to state around the country,  
16 does it not?

17 A. Yes.

18 MR. CHALOS: Objection to form.

19 THE WITNESS: Yes. But very important, what  
20 FDA has said, and this is what FDA's role says, is you  
21 can only engage in this kind of activity, you know, if  
22 you have valid prescriptions.

23 FDA -- what constitutes a valid prescription, I  
24 will agree with you, I mean, one could look to state  
25 law. But there has to be a valid prescription.



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1                   **MR. GIDEON:** Q. Okay. Now, with respect  
2 to all of the material that you have looked at from  
3 2002, did any of the FDA employees take the step to  
4 see if any of these products were covered by a valid  
5 state prescription?

6                   A. I don't -- I don't see that. What FDA did was  
7 what you would expect FDA to do, which was, I mean, at  
8 the time there was a concern about the safety of certain  
9 products. FDA focused on the issue, and I think acted  
10 very appropriately, made sure that product was recalled.  
11 Right?

12                  Because understand at this moment in time --

13                  Q. What question are you answering?

14                  A. I'm -- you are asking me about whether -- what  
15 FDA's role was.

16                  Q. No, I didn't.

17                  A. Yes, you did.

18                  Q. I didn't ask that question at all. I said did  
19 they check to see whether or not there were valid  
20 prescriptions. You answered that and said there's no  
21 evidence that they did, and then you just started  
22 talking.

23                  A. No, I didn't start talking.

24                  MR. CHALOS: Object to the form. There's not a  
25 question.

1                   Excuse me. Object to the form.

2                   MR. GIDEON: That's true. There is no  
3 question, but he is just extolling something, sharing  
4 with us at a thousand bucks an hour. And I really must  
5 insist on you answering my questions.

6                   MR. CHALOS: Don't answer. Object to the form.  
7 That's not a question. Object to the admonition.

8                   Hang on. Let him ask a question, please.

9                   MR. GIDEON: Q. Yeah. Now that we know  
10 they didn't check, why didn't they, if that's so  
11 important?

12                  MR. ARBITBLIT: Object to form.

13                  MR. CHALOS: Object to the form.

14                  MR. GIDEON: Q. Why didn't they take the  
15 time to check and see if this volume of product was  
16 covered by patient-specific prescriptions?

17                  MR. ARBITBLIT: Object to form.

18                  THE WITNESS: Exactly the answer I gave you  
19 before when you cut me off. I gave you an answer.

20                  MR. GIDEON: Q. I --

21                  A. Yes, you did.

22                  Q. Okay. What is the answer, then?

23                  A. Read back what my answer was. What I said was  
24 the reason -- what FDA was doing at this time, right,  
25 was what FDA should have been focused on, which was



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1 to -- and what its clear authority was, certainly with  
2 FDAMA -- if the product was contaminated, FDA had a  
3 responsibility to get that product off the market and  
4 get that product recalled. That's what FDA did. Okay?

5 The state Board of Pharmacy -- I mean, yes, you  
6 are right, I very much wish, okay, that this whole  
7 scheme that your client and the -- and NECC were engaged  
8 in were -- was discovered and exposed. That would have  
9 been very nice.

10 That -- being able to show that there was this  
11 scheme of providing prescriptions or prescription order  
12 forms or lists when that was the key safeguard, and NECC  
13 was doing this without, your client was facilitating, do  
14 I wish that that would have been uncovered? Absolutely.  
15 It was not.

16 MS. MARTINEZ: Objection. Nonresponsive.

17 MR. GIDEON: Q. Was my client doing  
18 business with NECC in 2002?

19 A. No, but your client was --

20 Q. Were they doing business in 2003 --

21 A. No.

22 Q. -- when the FDA was still there?

23 A. No.

24 Q. So why don't you answer my question. Why  
25 didn't the FDA check to see if there were

1 patient-specific prescriptions on hand for all this huge  
2 volume of product in 2002 and 2003 once the contaminated  
3 product that had made some folks in California deathly  
4 ill was off the market? Why didn't they check?

5 MR. CHALOS: Object --

6 THE WITNESS: For the exact --

7 MR. CHALOS: Hang on one second.

8 Object to the form. Misstates the evidence in  
9 the case and compound.

10 MR. ARBITBLIT: And asked and answered.

11 THE WITNESS: Because FDA focused on what FDA  
12 should focus on, and the authority it had. The  
13 authority -- I mean, at this time, right, I mean,  
14 depending on whether FDAMA is in effect or not, the one  
15 clear authority it had, right, was to make sure that any  
16 filthy, putrid or decomposed product that may be  
17 injurious was off the market. That's what FDA focused  
18 on.

19 It concluded that NECC was a compounder and  
20 turned over that regulation to the Massachusetts Board  
21 of Pharmacy.

22 MR. GIDEON: Okay.

23 MR. ARBITBLIT: Before you move on, if you are  
24 moving on, I have something to read for completeness.  
25 And it's a reference to something that the witness spoke

1 about. It's at schedule 5 of his report, sub (e), FDA  
2 Investigation Report, October 24, 2002 to February 10,  
3 2003, at page 14, which is also marked as S0476.

4 Question No. 2 of the FDA investigation: Does  
5 the NECC continue to fill patient-specific prescriptions  
6 for each compounded product dispensed?

7 Answer: NECC dispenses and prepares products  
8 in bulk for administration to individualized patients  
9 pursuant to a receipt of a valid prescription from a  
10 prescriber, end quote.

11 MR. GIDEON: Q. Do you know if that  
12 representation by NECC was intentionally false or  
13 not?

14 A. I don't believe I've seen the prescription  
15 databases and the prescriptions that NECC had at the  
16 time, so I don't know that. I know it was false later  
17 on. It would have been false later on.

18 Q. And when did it first become false? When did  
19 the representations by NECC about getting  
20 patient-specific prescriptions first, to your knowledge,  
21 become just an utter lie.

22 MR. CHALOS: Object to the form.

23 THE WITNESS: So on -- based on the --

24 MR. GIDEON: Q. The question is when.

25 A. I understand exactly.

1 MR. CHALOS: Object to the form.

2 THE WITNESS: So based on the record that I  
3 have seen, okay?

4 MR. GIDEON: Q. I'm directing it to you as  
5 the witness, not a record somebody else has seen.  
6 So that's implicit.

7 MR. CHALOS: Object to the commentary. There's  
8 not a question pending at this point.

9 MR. GIDEON: Q. When? When did their  
10 representations about receiving patient-specific  
11 prescriptions become an utter lie?

12 MR. CHALOS: Object to the form. Misstates the  
13 record.

14 THE WITNESS: So the record that I have seen --

15 MR. GIDEON: Q. Okay. The record you've  
16 seen. We've got that.

17 A. But -- but --

18 MR. CHALOS: Object to the commentary. There's  
19 not a question pending, sir.

20 THE WITNESS: Hold on. I -- what I'm trying to  
21 help you get -- I mean, because the record --

22 MR. GIDEON: Q. Doctor, you are not  
23 helping anybody because you are --

24 A. I'm trying to answer your question.

25 Q. -- you are not answering anything.



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1                   MR. CHALOS: Objection. Argumentative.

2                   MR. GIDEON: Q. Every response --

3                   MR. ARBITBLIT: Let's take a break.

4                   MR. GIDEON: Q. -- you provide, there's a  
5 long windup, and then a lot of words, and very  
6 seldom an answer.

7                   MR. CHALOS: Objection to the form.

8                   C.J., quit whining. Let's take a break.

9                   MS. MARTINEZ: There's a question pending.  
10 Hold on.

11                  MR. CHALOS: There is no question pending --

12                  MR. ARBITBLIT: He stopped his question with a  
13 diatribe.

14                  MR. CHALOS: There's no question pending.  
15 Let's take a break.

16                  MR. GIDEON: We're going to get an answer to  
17 the question. The witness says he wants to answer the  
18 question --

19                  THE WITNESS: I would like to answer the  
20 question.

21                  MR. GIDEON: -- so let's get an answer.

22                  MR. ARBITBLIT: Well, then reask the question  
23 and don't interrupt him when he's giving you --

24                  MR. GIDEON: You are interrupting --

25                  MR. ARBITBLIT: There's no question pending,



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1           Doctor.

2                 Ask the question.

3                 MR. GIDEON: You are interrupting a gentleman  
4                 that wants to talk some more.

5                 Go ahead.

6                 MR. ARBITBLIT: Dr. Kessler, wait for a  
7                 question.

8                 MR. GIDEON: Q. No, no, no. Go ahead and  
9                 speak. Share with them what you wanted to say.

10                MR. ARBITBLIT: There's a question. Go ahead.

11                THE WITNESS: You asked me when. When I have  
12                 evidence of the fraud.

13                MR. GIDEON: Q. That's not what I asked.  
14                 I asked you when did it become apparent to you from  
15                 the record you've seen, not the record somebody else  
16                 has seen, that the representations of having a  
17                 patient-specific prescription made by NECC were just  
18                 an utter lie? When?

19                MR. ARBITBLIT: Object to form.

20                MR. CHALOS: Object to the form.

21                THE WITNESS: The documents that I have show,  
22                 right, that false and no prescriptions were certainly  
23                 done in the 2011 -- I mean, in the NECC, the  
24                 prescription order forms, 2012, sorry, period of time.  
25                 Those are -- that's the evidence in the record that I

1 have. Okay?

2 I do not have, in the record, evidence of  
3 prescription logs, et cetera, other than the  
4 prescription logs from STOPNC. Those prescription  
5 documents, call them -- I'll just testify whether  
6 they're prescriptions or fake prescriptions or meant to  
7 be prescriptions, others can testify -- that, clearly  
8 evidences STOPNC, Saint Thomas Outpatient and NEC were  
9 engaged in a fraud. I don't know -- engaged in  
10 wrongdoing. Those were not prescriptions. We know  
11 that.

12 That's what I have in this record. I do not  
13 want to represent, okay, because I have not seen other  
14 cases, other instances earlier on, right, where there  
15 was orders without valid prescriptions.

16 MR. GIDEON: Q. Did these folks not give  
17 you a copy of the investigation of NECC by the Board  
18 of Registration and Pharmacy of the products they  
19 sold to the Massachusetts Eye and Ear Clinic?

20 MR. CHALOS: Object to the form.

21 THE WITNESS: I believe I saw something about  
22 potency and Mass Eye and Ear. Yes, I believe I did see  
23 something.

24 MR. GIDEON: Q. Good. Did you tell me  
25 earlier that you actually read the transcript of the

1 Penta deposition or did you only see the exhibits?

2 A. I only -- let me be exactly clear. I used the  
3 Penta exhibits to be able to find citations that are  
4 cited in Dr. Miller's report. Because I didn't have  
5 Dr. Miller's CV, so I had the footnotes. But I  
6 didn't -- so I looked at the documents in Dr. Miller's,  
7 and I used the Penta documents to be able to find what  
8 Dr. Miller was citing.

9 Q. Well, did you see, among the Penta exhibits,  
10 the emails between Cadden and Conigliaro confirming that  
11 for all of the monthly product sold to the Massachusetts  
12 Eye and Ear Clinic, there were no patient-specific  
13 prescriptions?

14 A. I'd have to review. I just don't know.

15 Q. Does that ring a bell?

16 A. I mean, Mass Eye and Ear, but that specific  
17 statement does not ring a bell.

18 Q. Do you recall those exhibits where once Mass  
19 Eye and Ear complained about the problems with  
20 subpotency --

21 A. Yes.

22 Q. -- of these ophthalmic syringes that they were  
23 shipping over every month, and they anticipated an  
24 investigation by the Board of Registration and Pharmacy,  
25 Cadden emails Conigliaro and says we're going to have to



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1 figure out a way to get patient names. And Cadden says  
2 to Conigliaro, unless she's a complete fool she'll know  
3 what we're up to.

4 Do you remember those emails?

5 A. What's --

6 MR. CHALOS: Hold on a second.

7 Object to the form. Object to the  
8 paraphrasing. If you have a document, I'd suggest you  
9 show it to him if you want to ask a specific question.

10 THE WITNESS: I remember similar kinds of  
11 emails, perhaps that one. I did read the DOJ criminal  
12 information.

13 MR. GIDEON: Q. The indictment?

14 A. The indictment. And I believe there are  
15 certain emails that are referenced to that dealing with  
16 this scheme or this fraud.

17 Q. Was the Massachusetts Eye and Ear Clinic  
18 involved in a scheme and a fraud with NECC?

19 MR. CHALOS: Object to the form.

20 THE WITNESS: I don't have the evidence of what  
21 they submitted. I do not know what they submitted to  
22 NECC. I only know what STOPNC submitted to NECC. If  
23 you want to give me the record of those prescriptions,  
24 I'd be happy to look at them.

25 MR. GIDEON: Q. There are no

1 prescriptions.

2 MR. CHALOS: Hang on. Object to the form.

3 THE WITNESS: Did they submit false  
4 prescriptions?

5 MR. GIDEON: Q. There are no  
6 prescriptions. They just ordered.

7 A. Did they submit false prescriptions?

8 Q. They just ordered product. One hundred vials a  
9 month.

10 MR. CHALOS: Hang on. Object to the form.

11 THE WITNESS: Then that would be different.

12 That would be a different set of facts. Because what  
13 STOPNC did here was to facilitate this scheme of this  
14 wrongdoing by signing these things called prescription  
15 order forms and giving names when they weren't  
16 prescriptions and there wasn't a physician-pharmacist  
17 relationship. That allowed NECC to enter these names in  
18 a database and together perpetuate this wrongdoing.

19 MR. GIDEON: Q. Okay. Well let's take a  
20 look at the --

21 THE WITNESS: Could we take a break?

22 MR. ARBITBLIT: We can.

23 MR. GIDEON: Sure. And when we come back,  
24 we'll talk about this precise subject you've just  
25 brought up with your answer.



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1                   **THE WITNESS:** Thank you.

2                   **THE VIDEOGRAPHER:** This is the end of disc  
3 No. 3, volume 1.

4                   We are off the record at 2:26 p.m.

5                   (Recess taken from 2:26 PM to 2:38 PM)

6                   (Whereupon, Exhibit 1254 was marked for  
7 identification.)

8                   **THE VIDEOGRAPHER:** This is the beginning of  
9 disc No. 4, volume 1.

10                  We are back on the record at 2:38 p.m. You may  
11 proceed.

12                  **MR. GIDEON:** Q. The documents in front of  
13 you are exhibits to the deposition of Mario Giamei.  
14 Were you previously provided with those exhibits?

15                  A. They may be in the Penta documents. I don't  
16 recall specifically. I don't recall.

17                  Q. Okay. Take a look at them.

18                  A. What, specifically, would you like me to read?

19                  Q. Just want you to read these documents.

20                  A. Okay.

21                  Q. And then I'll ask you questions once you've  
22 taken a look at each of these emails.

23                  A. Okay.

24                  Q. Take a look at --

25                  A. I'm not done. I apologize.

1           Q. Will you lift your head up when you've finished  
2 looking at these emails?

3           A. I'd be happy to.

4               My head is up.

5           Q. Okay. Did you know before I handed you this  
6 group of documents that Saint Thomas Outpatient  
7 Neurosurgery Center refused the NECC request for patient  
8 names?

9           MR. CHALOS: Object to the form.

10           THE WITNESS: I know -- I don't know it in the  
11 way that was phrased. No, I didn't know that. I --  
12 this does -- some of this jives with what I've read in  
13 the Debra Schamberg testimony.

14           MR. GIDEON: Q. You can see on MEDICAL  
15 SALES MANAGEMENT 82, which is the second page, that  
16 in that Debbie Schamberg refused the Medical Sales  
17 Management request for patient names.

18           MR. CHALOS: Which date of the email are you  
19 looking at?

20           MR. GIDEON: Second page.

21           MR. CHALOS: This is the June 13th, 2011 email?

22           MR. GIDEON: Yes. MEDICAL SALES MANAGEMENT 82  
23 at the bottom of the page.

24           MR. CHALOS: I see.

25           THE WITNESS: Do you have a complete document?

1                   MR. GIDEON: Q. What do you mean complete  
2 document?

3                   A. Because these aren't consecutive Bates numbers.  
4 So could you do me the favor and give me a complete  
5 document?

6                   Q. I have a document in front of you that is an  
7 email of June 13th, 2011, from Bob Ronzio, who headed  
8 Medical Sales Management to Barry Cadden.

9                   You know who Barry Cadden is, don't you?

10                  A. I do, sir.

11                  Q. Okay. Before today, before I handed you this  
12 Medical Sales Management page 82, did you know that  
13 Debbie Schamberg, on behalf of STOPNC, refused to  
14 provide the patient names?

15                  MR. CHALOS: Object to the form. Misstates the  
16 testimony and the document.

17                  THE WITNESS: I was aware of testimony, and I'd  
18 have to refresh it, from Debbie Schamberg about  
19 discussions about giving patient lists. That's what I  
20 am aware of. I don't -- I don't recall, I have to look  
21 in that deposition to her testimony. I don't recall  
22 where she says that she refused to do it.

23                  And I don't see -- correct me where I am -- she  
24 said she spoke to her administrator and they have a  
25 strict policy on providing patient information out of

1 the office. That's, you know, obviously -- I mean, I  
2 think there was some discussion about HIPAA also in the  
3 deposition.

4 I told them we are completely HIPAA compliant,  
5 and we maintain a very strict privacy system under our  
6 HIPAA policy. They're not willing to move forward.

7 The record I show is that, in fact, she didn't  
8 refuse. That, in fact, the list did go in. That's what  
9 I see in the record.

10 Certainly at certain points in time lists did  
11 go in. So it's un -- it's certainly not the case that  
12 she refused to give -- or let me not state exactly  
13 who -- you made a statement that Schamberg refused. I  
14 can't tell you who at STOPNC did this. But clearly  
15 lists went in, so the bottom line is they didn't refuse.

16 Q. So your careful analysis of the facts are that  
17 STOPNC provided lists of patient names during calendar  
18 year 2011?

19 A. No, I --

20 MR. CHALOS: Object to the form.

21 THE WITNESS: No, I think I -- let me pull  
22 those lists very specifically, if I may. If someone  
23 could help me get those patient lists and those  
24 prescription order forms. Let me just pull them.

25 MR. GIDEON: Q. Do you have any --

1           A. Let -- let -- let -- let --

2           Q. Do you have any lists --

3           A. I'm still answering the question, please.

4           Q. Do you have any lists of patient names being  
5 provided throughout the entire year, calendar year 2011?

6           A. Now, so let me just finish answering this. And  
7 let me just pull --

8           Q. Here's the question. Any patient names being  
9 provided during calendar year 2011?

10          A. So I think there are lists. Let me just get  
11 the footnote, then I'll pull the actual. Just give me  
12 one second.

13           Thank you, sir.

14           So the answer to your question is, from what I  
15 can determine here, that it was done in 2012.

16          Q. That's not the question.

17           The question was, do you have any evidence at  
18 all that any patient names were provided by STOPNC to  
19 NECC during the entire calendar year 2011?

20          A. Hang on one second, please.

21           If someone could kindly just pull for me STOPNC  
22 0060-64. And actually, let's start from 0056. Mine are  
23 just out of order here. And I apologize. These are  
24 not -- I can get that. That will give you the dates.

25           THE REPORTER: Would you repeat the first



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1 number again, please.

2 THE WITNESS: Sure. I've asked for  
3 STOPNC\_0060-64, and beginning 0056 to 59, 65 to 67. If  
4 I can just pull the documents in footnote 14 of my  
5 report, I can be exact in that answer. If someone could  
6 help me just pull -- see if they have documents.  
7 Because mine just happen to be out of order. I must  
8 have pulled them.

9 So the answer to your question is no -- no, I  
10 don't see it in 2011, I see it in 2012.

11 Q. As you look at the document that's in front of  
12 you, the email traffic we were just talking about --

13 A. Yes, sir.

14 Q. -- recite the exhibit number again, please.  
15 The cover number.

16 A. In this case, 1254.

17 Q. Okay.

18 A. Previously 683.

19 Q. Okay. If you will look at MEDICAL SALES  
20 MANAGEMENT 252, it's the next to last page. It's only  
21 three lines. Shouldn't take too long.

22 A. Yes. I've seen it. I read it initially.

23 Q. Right. In referring to Saint Thomas Outpatient  
24 Neurosurgical Center it says: This facility has an  
25 order in for No. 500 Methly 80 of 1 milliliters and

1       No. 10 Beta Repo pf 2 milliliters.   Quote: They have  
2       been waived from providing patient names as of  
3       6/13/2011, period, end quote.   Please advise how I  
4       should proceed with this order.   Thank you, Steven  
5       Sanda.

6                   And this goes to Bob Ronzio, correct?

7       A. That's what it says.

8       Q. Did Barry Cadden or Bob Ronzio have the  
9       authority to waive the requirement for patient-specific  
10      prescriptions?

11      A. Patient prescription --

12      MR. CHALOS: Object to the form.

13      THE WITNESS: Patient-specific prescriptions  
14      were essential if you were going to order -- deliver  
15      prescription compounded drugs.

16      MR. GIDEON: Q. My question again: Did  
17      Barry Cadden, Robert Ronzio, or anybody at NECC have  
18      the authority to waive the requirement for  
19      patient-specific prescriptions?

20      MR. ARBITBLIT: Object to form.

21      THE WITNESS: I think my answer is the exact  
22      same answer that I gave you before, and I'm trying to  
23      pull it up. Give me a second.

24      MR. GIDEON: Q. What is it?

25      MR. ARBITBLIT: Asked and answered.



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1                   **THE WITNESS:** Let me give you -- pull up my --  
2                   Can you help me get to the bottom? I guess --  
3                   is there -- thank you.

4                   Wait. My -- my answer --

5                   **MR. GIDEON:** Q. The screen in front of you  
6                   is a copy of the transcription by the court reporter  
7                   to your left, isn't it?

8                   A. Yes. And I just want to read. My answer was  
9                   patient-specific prescriptions were essential if you  
10                  were going to order or deliver prescription compounded  
11                  drugs.

12                  Q. Okay.

13                  A. So they were essential.

14                  Q. Okay. I know they're essential according to  
15                  you, but my question --

16                  A. It's not just according to me. It's according  
17                  to -- should be according to any definition of  
18                  compounding that you could read or exists.

19                  Q. The question is, did Barry Cadden, Robert  
20                  Ronzio, Doug Conigliaro, or anybody at NECC have the  
21                  authority to waive patient-specific prescriptions?

22                  A. Pursuant to what?

23                  Q. Any authority. Did they have the authority --

24                  A. Pursuant to federal law?

25                  Q. State law. Federal law.



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1           A. There was a --

2           MR. CHALOS: Object to the form.

3           THE WITNESS: There was a requirement -- excuse  
4 me.

5           MR. GIDEON: Q. Could you start that  
6 again, because it wasn't clear.

7           A. There is a requirement, right, as I said, that  
8 if you are going to order or you're going to deliver  
9 compounded drugs, you have to have a patient-specific  
10 prescription.

11          Q. Okay. So did Barry Cadden have the authority  
12 to waive that requirement?

13          A. Barry --

14          MR. CHALOS: Object to the form.

15          THE WITNESS: -- Cadden did not have the  
16 authority to waive that requirement, nor did STOPNC have  
17 the authority to submit false names.

18          MR. GIDEON: Q. Okay. Just had to get  
19 that in there, didn't you?

20          MR. CHALOS: Object to the form.  
21 Argumentative.

22          MR. GIDEON: Q. Do you consider yourself  
23 an advocate or an expert?

24          A. I am very much an expert.

25          Q. In what?



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1           A. I think I probably know more about the federal  
2 regulation of drugs than probably many people in this  
3 country. I'm probably as, you know, as expert on that  
4 question.

5           Your questions are -- I mean, what your -- what  
6 you're doing, and you are certainly entitled to do that,  
7 you are asking me for a very narrow question, right,  
8 that gives you an answer.

9           Q. I'm asking you for a very narrow question?

10          A. You are asking a narrow question, and what I am  
11 doing is putting it in context. Right?

12          Q. What you are doing is not answering the very  
13 narrow question.

14          MR. CHALOS: Objection. Argumentative.

15          THE WITNESS: I --

16          MR. CHALOS: Wait for a --

17          MR. GIDEON: Q. I want you to continue  
18 telling us the areas where you see yourself as a  
19 real expert.

20          MR. CHALOS: Object to form.

21          MR. GIDEON: Q. You've told us about  
22 federal regulation of drugs. Are there any other  
23 areas where you see yourself really as an expert?

24          MR. ARBITBLIT: Object to form.

25          THE WITNESS: Yes.



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1                   MR. GIDEON: Q. What are they?

2                   A. Multiple areas.

3                   Q. What are they?

4                   A. I know I was intimately involved in  
5 compounding, in the requirements for compounding.

6                   Q. Okay.

7                   A. I've run a hospital. I've been in charge of  
8 pharmacy and therapeutic committees. I've done drug  
9 formularies. I've -- I understand safeguards of patient  
10 needs. I know safeguards the patient needs to protect  
11 them. I know the importance of an integrity of a  
12 prescription drug system.

13                  Q. Okay. Well, the order forms that you were  
14 showing us earlier that -- when I asked you was there  
15 one in 2011, and ultimately you said no, and you said  
16 there are some in 2012, were those order forms approved  
17 by the Massachusetts Board of Pharmacy?

18                  A. I have not seen any document one way or the  
19 other that, quote, approves these forms.

20                  Q. Who gave Debbie Schamberg the order forms that  
21 you have looked at?

22                  A. I'd have to check her deposition. I'm not  
23 sure -- I'd have to check and see exactly what she  
24 testified to. I don't remember exactly.

25                  Q. Do those order forms that you've been looking

1 at a few moments today, do they constitute an adequate  
2 prescription order under Tennessee law?

3 A. I would let you have other experts who are  
4 experts on Tennessee.

5 Q. Are you an expert on Tennessee law?

6 A. I would not want to opine on Tennessee pharmacy  
7 law. I can tell you that.

8 Q. That answers my question. Are you an expert in  
9 Tennessee law, and your answer is no?

10 A. What I specifically answered was that I am  
11 not -- I will certainly yield, let others answer who  
12 enforce the Tennessee law. They can testify whether  
13 this was a valid prescription.

14 Q. There may be lots of people who have opinions,  
15 but that isn't even close to what I asked you.

16 I asked you whether or not you considered  
17 yourself to be an expert on Tennessee law, and it's  
18 subject to an incredibly simple answer; either yes, you  
19 do or no, you don't.

20 MR. CHALOS: Object to the form.

21 Argumentative.

22 THE WITNESS: Yeah. I am -- for Tennessee law,  
23 I will leave that to other experts in this case.

24 MR. GIDEON: Q. Well, do you know of a  
25 person who claims to be an expert on Tennessee law

1       in this case?

2                   MR. CHALOS: Object to the form.

3                   THE WITNESS: I know that there's other  
4       testimony that I've read, whether this is a valid  
5       prescription form. I mean, in depositions there are  
6       people who have opined whether this is a valid  
7       prescription form or not who are familiar with Tennessee  
8       Board of Pharmacy practice laws. I will leave that to  
9       them, to the question of whether this was a valid or  
10      not.

11                  Certainly I can tell you, right -- it's  
12       certainly within my competence that Mickey Mouse is  
13       not -- could not be -- when it's clearly not a patient,  
14       that can't be a valid prescription. That, I can tell  
15      you with certainty.

16                  Q. And that would be openly apparent to anybody,  
17       wouldn't it?

18                  MR. CHALOS: Object to the form. Calls for  
19       speculation.

20                  THE WITNESS: I had to go check and make sure.  
21       I mean, you only know from deposition testimony, right,  
22       there's no patient.

23                  MR. GIDEON: Q. The name Mickey Mouse is  
24       apparent to everybody in this room as something that  
25       doesn't describe a living, breathing patient.

1       That's obvious, isn't it?

2           MR. CHALOS: Object to the form. Calls for  
3 speculation.

4           THE WITNESS: We can go look -- we can go look  
5 up and see if there's anybody in this United States and  
6 look at the phone book and see whether -- I've  
7 actually -- I actually --

8           MR. GIDEON: Q. You've done that?

9           A. Well, I actually looked here --

10          Q. Did you charge these folks for doing that?

11          MR. ARBITBLIT: Object to the form.

12          THE WITNESS: You're -- if you would like to  
13 stop now, I'll stop charging. There won't be any other  
14 payment. You are asking me all these questions, so I'm  
15 sitting here --

16          MR. GIDEON: Q. Did you search the name  
17 Mickey Mouse and charge these folks for it?

18          A. I wanted to know specifically. I read the  
19 deposition of Debra Schamberg where she stated that  
20 Mickey Mouse was not a real name.

21          Q. So why did you need to verify that by a name  
22 search in the state of California?

23          A. Because I don't -- I'm sorry, I didn't do a  
24 name search in the state of California. I read that  
25 in -- you're asking me whether there's anyone in the

1       United States, right, who is named Mickey Mouse. I  
2       don't know that.

3           Q. I didn't ask that.

4           A. You said wasn't it apparent that this was a  
5       false name.

6           Q. Sure.

7           A. Right? It certainly appeared that way. But  
8       you can't sit here and tell me that you know there's no  
9       one named Michael Mouse that goes by Mickey.

10          Q. So let me make sure I understand on video, did  
11       you actually search to see if there are people by the  
12       name of Mickey Mouse?

13          A. No. I read Ms. Schamberg's testimony.

14          Q. Uh-huh.

15          A. She said that Mickey Mouse was not a real  
16       person. That that was not meant to be a real person.  
17       That testimony, I read.

18          Q. And did you recall, as you read Debbie  
19       Schamberg's testimony, that the term was used to cover  
20       the time frame when John Culclasure was not available at  
21       STOPNC but was at another location?

22          A. On the floor, I think she referred to.

23          Q. Do you recall that testimony too?

24          A. Exactly. I think she said when he was  
25       scheduled for another floor.



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1 Q. Correct.

2 A. But why would you then submit that name as a  
3 prescription?

4 Q. Well, the question is through 2011, time frame  
5 we're talking about, we have established that there were  
6 no submissions of any names or any prescriptions; is  
7 that not correct?

8 MR. CHALOS: Objection.

9 THE WITNESS: So what I --

10 MR. GIDEON: Q. Is that not correct?

11 A. So I did not -- I said the list appears to be  
12 2012.

13 Q. Sure.

14 A. The prescription order form, I've -- I have  
15 multiple prescription order forms that do not have  
16 names.

17 Q. Not a one?

18 Now --

19 MR. CHALOS: Hold on a sec.

20 Objection to the misrepresentation.

21 MR. GIDEON: Q. Throughout 2011, since  
22 there were no names on any of the order forms,  
23 should NECC have dispensed product to Saint Thomas  
24 Outpatient Neurosurgery Center?

25 MR. CHALOS: Object to the mischaracterization.

1                   MR. GIDEON: Why don't you throw in  
2 argumentative too. That will help.

3                   MR. CHALOS: Object to that. That's  
4 argumentative.

5                   MR. GIDEON: Go ahead.

6                   MR. CHALOS: C.J., you are not going to get  
7 anywhere -- excuse me. You're not going to get anywhere  
8 acting that way. You are frustrated, I get it, but it's  
9 because of your questions.

10                  MR. GIDEON: No. You know what is going on  
11 here, Mark? You like to talk, you say things that mean  
12 nothing. But the bottom line is your witness will not  
13 answer a question directly, and we're just going to have  
14 to continue plugging along. But your commentary is so  
15 far off the mark, it's not even half serious.

16                  MR. CHALOS: Right. Well, I object to the  
17 colloquy here.

18                  MR. GIDEON: Q. So here's the question  
19 again.

20                  A. Thanks.

21                  Q. There are no names on any order sheet through  
22 calendar year 2011.

23                  MR. CHALOS: Objection. Asked and answered.

24                  MR. GIDEON: Q. I have taken the time to  
25 show you, with specific documents that perhaps the

1 people that engaged you didn't share with you, maybe  
2 they did and you don't remember them, that STOPNC  
3 refused to provide any patient names, and then the  
4 folks at NECC just decided to waive the requirement  
5 for any names.

6 MR. CHALOS: Objection to the form.

7 MR. GIDEON: Q. Now, given that -- given  
8 that -- here comes the question.

9 MR. CHALOS: Okay. Object to everything before  
10 the question then.

11 MR. GIDEON: Q. Should NECC have shipped  
12 methylprednisolone acetate to Saint Thomas  
13 Outpatient Neurosurgery Center in Nashville,  
14 Tennessee?

15 MR. CHALOS: Object to the form.

16 THE WITNESS: The answer is NEC should not have  
17 shipped, nor should STOPNC filled out prescription order  
18 forms to order the form (verbatim). None of that  
19 conduct should have taken place. NEC should not have  
20 shipped. STOPNC should not have ordered and filled out  
21 those forms.

22 MR. GIDEON: Q. Do you have -- do you have  
23 information that's been provided to you that  
24 reflected that any of the purchasers from NECC, in  
25 calendar year 2011 or 2012, actually obtained



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1 product with patient-specific prescriptions?

2 MR. CHALOS: Object to the form.

3 THE WITNESS: All I know is that in 2011, I do  
4 have a form that's a prescription order form where a  
5 name of the patient is blank, and those were filled.

6 MR. GIDEON: Q. Go ahead and read him the  
7 question back. Maybe you can get his attention to  
8 answer the question.

9 MR. CHALOS: Objection to the form.

10 Argumentative.

11 MR. GIDEON: Right. Misleading.

12 Go ahead. Read him back the question.

13 MR. CHALOS: Actually, that time you didn't try  
14 to mislead.

15 MR. GIDEON: Go ahead and answer the question  
16 this time. Maybe when she reads it back to you, you  
17 will answer it.

18 MR. CHALOS: Object to the form.

19 (Record read as follows: Do you have  
20 information that's been provided to you that  
21 reflected that any of the purchasers from NECC,  
22 in calendar year 2011 or 2012, actually  
23 provided product with patient-specific  
24 prescriptions?)

25 THE WITNESS: The answer is, what I have



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1 available is prescription order forms without the names  
2 of patients.

3 MR. GIDEON: Okay. I'll ask her to read it  
4 back to you again.

5 (Record read as follows: Do you have  
6 information that's been provided to you that  
7 reflected that any of the purchasers from NECC,  
8 in calendar year 2011 or 2012, actually  
9 provided product with patient-specific  
10 prescriptions?)

11 THE WITNESS: The evidence I have are patient  
12 prescription order forms which say name of the patient  
13 that's left blank, that has a name of a doctor by  
14 STOPNC. So there's no patient-specific names on these  
15 forms.

16 MR. GIDEON: Q. Okay.

17 A. But there is a form that is a prescription  
18 order form where that is left blank.

19 Q. And that's not in compliance with the  
20 requirement for a patient-specific prescription, is it?

21 A. Certainly doesn't appear to be in compliance.  
22 If I asked for patient specific, it doesn't give any  
23 evidence of a pharmacist-physician interaction where  
24 care was given in deciding whether this  
25 preservative-free medicine should have been used.



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1           Q. Now, if -- are you familiar enough with the  
2         fungal meningitis outbreak to know that there were three  
3         bad batches?

4           A. Yes.

5           Q. There was one bad batch made May 21st, there  
6         was another bad batch made June 29th, and a third bad  
7         batch made August 10th, correct?

8           A. I didn't have the dates in my head. I knew  
9         there were three batches.

10          Q. I can tell you those are the three dates listed  
11         on the log formula worksheets.

12          A. And I don't dispute that.

13          Q. If a physician in Tennessee or New Jersey or  
14         Texas had written a patient-specific prescription for  
15         David Kessler for an epidural steroid injection, and  
16         NECC responded to that patient-specific prescription  
17         with a vial from one of these bad lots, you still would  
18         have been exposed to contamination, wouldn't you?

19           MR. CHALOS: Incomplete hypothetical.

20          Objection.

21           THE WITNESS: So that individual patient would  
22         have been exposed. But that decision, right, would have  
23         been the result -- that prescription was written, you  
24         know, with that name, and a specific decision was made  
25         to do Preservative-free, right, then you are willing to

1 take that risk.

2 MR. GIDEON: Q. Yeah.

3 A. Right? But the fact is, so you are right.

4 Maybe one patient would have been exposed where a  
5 physician says, you know, you have an allergy to benzyl  
6 alcohol. There's a specific reason I don't want to use  
7 benzyl alcohol. So you would make that decision, and  
8 you would make that risk benefit. One patient would  
9 have gotten harmed, not these dozens or hundreds of  
10 patients.

11 Because that decision making that goes into  
12 that prescription, right, would have had -- have a  
13 physician think through the question of do I want a  
14 preservative, do I not want preservative, which is  
15 better for my patient, right?

16 That was the whole goal of compounding. It was  
17 individual. One person may have been harmed if you --  
18 if somebody had to think through that, two people or  
19 three people, not 700 patients nationwide.

20 Q. Is there a limit on the number of  
21 prescriptions, patient-specific prescriptions that a  
22 physician can write?

23 MR. CHALOS: Object to the form. Incomplete  
24 hypothetical.

25 THE WITNESS: Sure. I would assume there's

1 a -- I mean, there has to be a basis to write a  
2 prescription.

3 MR. GIDEON: Q. My question is, is there a  
4 limit on the number of patient-specific  
5 prescriptions that a physician can write under state  
6 practice laws?

7 MR. CHALOS: Objection. Incomplete  
8 hypothetical.

9 THE WITNESS: I don't believe so. But again,  
10 I'm not going to opine on state law. I can -- what is  
11 clear, there is a limit, obvious -- obviously, to the  
12 number -- to the thinking process. If I have to go  
13 think, do I want this patient to have preservative free  
14 or not, that's a decision process that would have to be  
15 consciously made.

16 So, I mean, I would make that decision -- a  
17 physician would make that decision each and every time.  
18 I mean, if there was evidence that these patients had  
19 allergies and the risks, benefits -- there's a calculus  
20 that would have to go into that prescription that would  
21 be based on the needs of that patient.

22 So, in fact, I mean, the reality is here, that  
23 Culclasure did not, right, go through that thinking  
24 process at all with regard to whether preservative-free  
25 should be given to whether the risks and benefits --



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1 risks -- the benefits outweighed the risks.

2 MR. GIDEON: Q. Have you ever had a  
3 residency in anesthesia?

4 A. No. I was not an anesthesiologist.

5 Q. And I think we've covered much earlier that  
6 with the exception of being board certified in  
7 pediatrics at one point in time, you have not been  
8 boarded in any other occupations?

9 A. That's correct.

10 Q. You have never provided anesthetic or pain  
11 management services to a patient in the United States,  
12 have you?

13 A. Certainly as a pediatrician. I was involved  
14 in -- we did pain management before there was pain  
15 management, I mean, back -- certainly during my  
16 training.

17 Q. Let's take the relevant time frame. 2010 to  
18 2012, were you providing pain management services to  
19 adults anywhere in the United States?

20 A. I don't think -- I may have been consulted. I  
21 mean, on -- I'm an addiction expert and other things,  
22 and I may have been consulted. But the answer would be  
23 no, I think.

24 Q. What was the cost associated with registration  
25 with the FDA in 2010 and 2011?

1           A. The establishment fee under PDUFA?

2           Q. The cost associated if NECC had decided to step  
3 up and register as a manufacturer, what would it have  
4 cost them?

5           MR. CHALOS: Object to the form. Vague.

6           THE WITNESS: I'd have to look if there were  
7 specific requirements under PDUFA. It's easily  
8 available.

9           MR. GIDEON: Q. What were the fees?

10          A. I don't know the fees offhand. I was involved  
11 in the -- the enactment of PDUFA, but I've not looked at  
12 the fees specifically again. They're easily available.

13          Q. Since you stepped down as commissioner in 1997,  
14 have you registered any company as an FDA-registered  
15 manufacturer?

16          A. I certainly have been on the board of  
17 pharmaceutical companies that have registered.

18          Q. I didn't ask about boards or consulting. I  
19 asked whether you have ever taken the steps to register  
20 a company as an FDA-registered manufacturer.

21          A. I don't think I've filled out those forms, no.  
22 But I've been on boards that have done that.

23          Q. Before the outbreak in 2012, was any other  
24 policy guide issued other than 460.200, the one we  
25 talked about earlier?



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**NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY  
VIDEOTAPED DEPOSITION OF DAVID A. KESSLER, M.D. on 03/04/2016**

Page 244

1           A. Well, there were two policy -- two compliance  
2 policies.

3 Q. There was one during your tenure, and then  
4 there is this last is 460.200, correct?

5 A. Right.

6 Q. Were any others issued before September of  
7 2012?

8 A. I'm not aware of any others.

9 (Whereupon, Exhibit 1255 was marked for  
10 identification.)

11 MR. GIDEON: 21 U.S.C. 360(q)1.

12 Q. Exhibit 1255 should be right in your  
13 wheelhouse, Doctor. It's 21 U.S.C.A. § 360.

#### A. Inspection?

15 O. No. Exemption from registration.

16 A. Right.

Q. I want you to look at 360(g)1.

18 A. Yes.

19 Q. Which addresses the exemption from the duty to  
20 register.

21 A. Yes. Yes.

22 Q. Whose duty is it to register in the first  
23 place?

24 MR. ARBITBLIT: Object to form.

25 MR. GIDEON: O. It's not the purchaser's



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1       duty to register a manufacturer, is it?

2           A. No.

3           Q. It's not the patient's duty to register a  
4 manufacturer?

5           A. No.

6           Q. The manufacturer has the duty to register if  
7 they are a manufacturer, correct?

8           A. If there is a requirement to register.

9           Q. Okay. And before someone may introduce drugs  
10 in interstate commerce, under what circumstances must  
11 they register?

12          A. So we -- I have to check.

13           I want to go back. Certainly with regard to  
14 the introduction of new drugs.

15          Q. Okay. Can't put a new drug in interstate  
16 commerce without registration?

17          A. That's clear.

18          Q. Okay. Now secondly, even if you register, you  
19 may not introduce an adulterated drug in interstate  
20 commerce, correct, whether registered or not?

21          A. You are correct. That 501(a) that applies to  
22 old drugs does not allow you to introduce anything that  
23 would be contaminative or may be injurious to health.

24          Q. Correct.

25          A. That applies independent of the new drug



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1 provisions.

2 Q. Okay. Now, an exemption for registration is  
3 addressed at 21 U.S.C. 360(g)1, correct?

4 A. Right.

5 Q. Let's take it step by step in light of what you  
6 told me about your expertise in this area.

7 First of all, if you are a pharmacy and you  
8 want to avoid registration, you have to be operating in  
9 accordance with state law, don't you?

10 A. That's certainly the first sentence.

11 Q. First step?

12 A. Yes, sir.

13 Q. Now, if state law requires patient-specific  
14 prescriptions, and you're dispensing without them, then  
15 you're not operating in accordance with state law, are  
16 you?

17 A. Of course not.

18 Q. Okay. Second, if state law requires compliance  
19 with USP 797, and you are not complying with it, then  
20 you are not complying with state law, correct?

21 A. That's correct.

22 Q. Next it says, as part of this exemption from  
23 the duty to register, that you must dispense drugs upon  
24 prescription of practitioners licensed to administer  
25 drugs, end quote; isn't that correct?



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1           A. Let me see where you are reading. So these are  
2 if you are licensed to administer such drugs to patients  
3 under the care of such practitioners, right, you can be  
4 exempt, right? Is that what you are saying?

5           Q. You have to get a prescription from a  
6 practitioner who is licensed to administer drugs; isn't  
7 that right?

8           A. Yes.

9           Q. Well, if you're getting no prescription from  
10 somebody who is authorized to administer drugs, then  
11 that is another reason you cannot claim an exemption  
12 from registration; isn't that correct?

13          A. I'm sorry, a couple of double negatives in  
14 there.

15          Q. There's only one. But I'll run it by you  
16 again.

17          A. Just -- thanks.

18          Q. I'll do it again.

19           If a pharmacy is not obtaining prescriptions  
20 from somebody who's authorized to write them and  
21 administer drugs --

22          A. Right.

23          Q. -- then that pharmacy cannot claim exemption  
24 from a duty to register under 21 U.S.C. 360(g)1?

25          A. Right.

1           Q. It is clear, is it not, from the time we have  
2 spent covering this, that NECC should have registered  
3 with the FDA in calendar year 2011, isn't it?

4           A. I would want to just go back and understand the  
5 interaction of this section with FDAMA. I just would  
6 want to review that. I've not issued an opinion on  
7 that, and I just want to check the statute on FDAMA and  
8 see what does the exemption -- I'm just trying to think.  
9 I think in my head.

10           There's an exemption under new drugs. There's  
11 an exemption from the adulteration -- some of the  
12 adulteration, some of the exemption from the  
13 misbranding. I'd have to check. If you have the FDAMA  
14 statute, it will tell you specifically what the  
15 exemptions are. I just want to be careful that I don't  
16 misspeak.

17           Q. What do you mean? What do you want? Do you  
18 want us to pull up the old statute so you can --

19           A. Why don't you pull FDAMA.

20           Q. Give us a citation, we'll pull it up.

21           A. Just FDAMA. If you -- you give me FDAMA, I can  
22 tell you specifically.

23           Q. Is it in your materials?

24           A. Yeah, I can find it if you would like.

25           Q. Why don't you go ahead and do it if it's that

1 important to you answering that question.

2 A. I just want to make sure the interaction of  
3 this -- this section with the other sections before I  
4 speak. Happy to look at it. Let me just get it.

5 (Discussion off the record.)

6 MR. GIDEON: Would you lift the blotter up,  
7 too, just to see if it might not have gotten under  
8 there.

9 Thank you. Those have not been copied yet,  
10 have they.

11 MR. ARBITBLIT: They have not.

12 MR. GIDEON: Okay. Nice try.

13 MR. ARBITBLIT: We're off the record for a  
14 second. You can put this on the video.

15 It's the Pepsi syndrome.

16 MR. GIDEON: He is trying to wipe the record  
17 clean.

18 MR. ARBITBLIT: You got that. I'm trying to  
19 preserve the record, Counsel.

20 MR. GIDEON: He's spoliating right now.

21 MR. ARBITBLIT: Let the record reflect it was  
22 diet Snapple.

23 That's about as much as I can do, I think it's  
24 all still legible.

25 MR. GIDEON: Q. Can you give me the



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1 citation you are looking at?

2 A. Sure. So what I'm particularly interested in  
3 is, because as you -- what --

4 Q. I asked for the citations.

5 A. So I'm at S0343. I'm at section 503(a).

6 Q. You've been to law school, you know the  
7 citations for CFR and uniform -- United States Code.

8 A. This is --

9 Q. Begins with a number first --

10 A. This is 21 U.S.C. 353(a).

11 Q. Okay.

12 A. What I want to -- the reason I'm --

13 Q. I don't need you to tell us why. I just want  
14 you to finish your review so you can answer the  
15 question.

16 A. Yeah, I don't -- I know there are issues, both  
17 with -- as part of this section, both with inspections.  
18 Certainly with inspections on FDA's authority with  
19 regard to compounding. I'd have to look to be more  
20 specific to see if there's any interaction.

21 I don't see, based on this review, but I would  
22 want to be able to check because as we -- I know that  
23 compounders did resist and invoke certain sections of  
24 the act, both with regard to -- certainly with regard to  
25 inspections, and I think with regard to establishment.



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1     But I need to look at the legal basis for that before  
2     I'd opine.

3           Q. The FDA is responsible for protecting the  
4     public health by assuring the safety, efficacy and  
5     security of human and veterinary drugs, biological  
6     products, medical devices, the food supply, cosmetics,  
7     and products that emit radiation; isn't that correct?

8           MR. ARBITBLIT: Object to form.

9           THE WITNESS: Certainly that was true -- that  
10    was a true statement up until 1997.

11          MR. GIDEON: Q. And then what happened in  
12    1997?

13          A. Congress enacted FDAMA. So that would be a  
14    true statement, right, with regard to new drugs.

15          Q. Okay.

16          A. Because the safety and efficacy applies to new  
17    drugs. But Congress exempted, as we've been talking  
18    about, compounding from those new drugs. So that was  
19    why I objected to FDAMA when I was commissioner.  
20    Publicly.

21          Q. Okay. Now, did federal law stipulate  
22    acceptable formularies for ambulatory surgery centers  
23    licensed by the individual states?

24          A. No, they did not.

25          Q. Did Tennessee state law define what was an

1 acceptable formulary under an ambulatory surgery center?

2 A. Usually -- no, usually medical staffs do that.

3 Q. Did Tennessee law permit substitution for  
4 prescriptions in calendar years 2010 through 2012?

5 MR. CHALOS: Object to the form.

6 THE WITNESS: I would assume so, but I would  
7 want to pull the statute.

8 MR. GIDEON: Give me No. 13.

9 THE WITNESS: Thank you, Don.

10 MR. GIDEON: This is Exhibit 1256.

11 (Whereupon, Exhibit 1256 was marked for  
12 identification.)

13 MR. GIDEON: And this comes from PCCA075 to  
14 078. Documents produced by Pharmacy Compounding Centers  
15 of America, PCCA, produced to the PSC before we got  
16 involved in the litigation.

17 Q. I want you to take a moment and look at it, but  
18 I want to tell you what my specific question is.

19 A. Sure.

20 Q. And that is if NECC had complied with this  
21 policy to crimp and seal individual vials and then  
22 autoclave those individual vials for 20 minutes at  
23 121 degrees centigrade, 15 pounds per square inch, would  
24 that have prevented the fungal outbreak?

25 A. I'm not going to opine on that. An infectious

1 disease expert can do that.

2 Q. Do you know whether complying with this  
3 procedure would have killed the fungi in the vials in  
4 question?

5 A. I have not studied that question, sir.

6 Q. So you do not know?

7 A. I have no opinion on that.

8 Q. You told me earlier that you knew the  
9 difference between terminal sterilization and aseptic  
10 processing.

11 MR. ARBITBLIT: Object to form.

12 Mischaracterizes.

13 MR. GIDEON: Q. How does that  
14 mischaracterize what you said?

15 A. I said I can look that up pretty quickly. I  
16 didn't have it in my head.

17 Q. Okay. Well, the document that's in front of  
18 you right now, you have enough experience to know that  
19 what it advocates doing is terminal sterilization,  
20 correct?

21 A. I mean, the final stage of the product, that's  
22 what terminal means, yes.

23 Q. Correct. So if your ultimate production are  
24 individual vials, and those individual vials are subject  
25 to being autoclaved, that is terminal sterilization,

1       isn't it?

2           A. Again, I have no reason to dispute that  
3 definition.

4           Q. Okay. Now, at any time when you were at the  
5 FDA, as a means of dealing with compounders, did the FDA  
6 ever suggest that compounders should be required to  
7 report the volume of product they ship in interstate  
8 commerce as a way to figure out where the risk was  
9 greatest?

10          Do you want to hear the question again?

11          A. No, I think I got the question. I'm just  
12 trying to think.

13          Q. 1990 to 1997. And let me tell you one of the  
14 reasons why I asked you the question. You and I talked  
15 earlier about your testimony to Congress --

16          A. Yes.

17          Q. -- May 1st, 1996.

18          A. Yes, sir.

19          Q. And one of the things you said during that, and  
20 I'm going to give you a direct quote --

21          A. Sure.

22          Q. -- that I think you will recall.

23           Where is that case?

24           Yeah, here it is. May 1st, 1996. Your  
25 testimony was that you were concerned that compounding



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1 pharmacists would, quote, cheat and produce or compound  
2 drugs to replace manufactured drugs that were out there.

3 A. Can I see my testimony? I'll get it. I'll  
4 pull it up.

5 Q. Okay.

6 A. I'll get it. I remember there's two paragraphs  
7 in my testimony, if my recollection is --

8 Q. I believe I've quoted it directly.

9 A. Let me just pull it up.

10 Q. Okay.

11 A. Just give me a second, sir.

12 Q. Have the date correct, don't I?

13 A. That sounds right, but just give me one second.

14 If anyone has documents for paragraphs 41 -- I  
15 have 41 and 43. Here's my testimony. My memory is two  
16 paragraphs in a row. Let's see if I can get to it.

17 MR. ARBITBLIT: Do you have it?

18 THE WITNESS: You didn't read that correctly.

19 MR. GIDEON: Q. Did you say that you were  
20 concerned that compounding pharmacists would, quote,  
21 cheat? Did you use those -- did you use that term?

22 A. No. When you said it, it doesn't sound like  
23 me. That's why I --

24 Q. Were you asked the question, are you concerned  
25 whether compounding pharmacists will cheat and produce

1 or compound drugs to replace manufactured drugs that  
2 were out there, and you responded yes?

3 A. You would have to pull up -- show me -- I can  
4 show you exactly -- the testimony I have, I'm not  
5 disputing if there was a Q and A -- but let me give you  
6 the phrase. It's more likely --

7 Q. Are you looking at the testimony or prepared  
8 comments?

9 A. I'm looking at my prepared comments.

10 Q. Okay. But I'm talking about the Q and A with  
11 the members of the representative committee in question.  
12 And I actually think it was now senator, then  
13 congressman, Richard Burr from North Carolina. Does  
14 that ring a bell?

15 A. I certainly remember Congressman Burr well. So  
16 what I used was: It is likely to encourage large scale  
17 manufacturing under the guise of pharmacy compounding.

18 Q. Okay.

19 A. I don't know whether -- did I use the word  
20 cheat or did he use the word cheat? I don't remember.  
21 But I'm not going to dispute. If you have a record  
22 there, just show it to me. The Q and A.

23 MR. GIDEON: Do we have the Q and A?

24 MS. WEETER: We can play the video. I have it  
25 right here in front of me. We can play your testimony.

1                   THE WITNESS: I'd be happy to have it.

2                   MR. GIDEON: Q. Do you need that in order  
3 to answer my question?

4                   A. Again, I don't -- the words that I have in  
5 front of me are what I said. I'm not -- if you have a  
6 record, right, I trust you to represent that record  
7 correctly.

8                   Q. Okay. Well, Mark doesn't.

9                   A. Well, I have no doubt if you have the  
10 transcript and you have the video, what I said is what I  
11 said.

12                  Q. Well, let me -- let me tell you that I wouldn't  
13 have asked you the question unless I'd looked at the  
14 transcription of the Q and A. And what I've written  
15 down is that you responded "yes" when a congressman, and  
16 I believe it is then-Congressman Burr, asked you: Are  
17 you concerned that compounding pharmacists will cheat  
18 and produce or compound drugs to replace manufactured  
19 drugs that were out there. And my memory is you said  
20 yes.

21                  The premise for this is as a result of that,  
22 while you were still commissioner, did FDA ever take  
23 steps to determine volume of product being shipped out  
24 of state by compounding pharmacies?

25                  A. I don't know -- I don't recall whether we ever

1 did that specifically.

2 Q. Okay. Subsequent to your departure from the  
3 FDA sometime in --

4 A. Wait. Wait. No, of course we did. Because I  
5 cite in the compliance policy guide those numbers that I  
6 gave you earlier. So obviously we determined the  
7 volumes earlier. That was certainly under my watch.

8 Q. But that prior compliance policy guide that  
9 preceded 460.200 was 1990-what?

10 A. '2 --

11 Q. 1992 or 1993?

12 A. Or something like that. But we did that in  
13 anticipation while I was there, so we did do volume at  
14 that point.

15 Q. But after your response to the question from  
16 then-Congressman Burr, May 1st, 1996, did FDA take any  
17 action to try and determine who the big compounders were  
18 in terms of volume?

19 A. Understand that after that testimony, Congress  
20 changed the law and it was not based on volume, right.

21 Q. The compliance policy guide that we have spent  
22 a good deal of time on today refers to volume as one of  
23 the factors looked at in deciding whether someone is  
24 functioning like a manufacturer or as a compounding.

25 A. Correct me if I'm wrong, but you and I decided

1       that if you look, that the word had to do with limited  
2       prescriptions and based on the number of prescriptions  
3       you've had. That it did not specifically -- I mean,  
4       that was the paragraph you and I looked at, unlimited  
5       quantities. I asked you if there was another thing that  
6       said inordinate volume, you never gave me a citation.

7           Q. I'll give you a citation. You told me earlier  
8       you were an expert in all things involving regulation of  
9       manufacturers.

10          A. No, no, no --

11          Q. It is this language here --

12           MR. CHALOS: Object.

13           MR. GIDEON: Q. -- that says part of --  
14       part of what you would look to to determine if this  
15       company needed the careful scrutiny of the FDA --

16          A. Can I -- can I --

17          Q. -- I'm getting to it.

18          A. Can I have the document in front of me?

19           MR. CHALOS: I object to the form of the  
20       question.

21           THE WITNESS: Could I just have the document?

22           MR. GIDEON: Q. You've got the document.

23       Compliance policy guide.

24          A. I may have it, but I have a lot of documents in  
25       front of me. Give me the page.



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1 Q. Same page, 3.

2 A. Yes.

3 Q. For example, it's the same thing that -- where  
4 I had to count the lines for you.

5 A. This is line 10 that we talked about earlier.

6 Q. Yeah. Quote: For example, some firms receive  
7 and use large quantities of bulk drug substances to --  
8 here's the keywords -- manufacture large quantities of  
9 unapproved drug products to advance -- in advance of  
10 receiving a valid prescription for them, end quote.

11 Question --

12 A. That was --

13 Q. Question: From and after 2002, did the FDA  
14 take any steps to see which compounders were actually  
15 making large quantities of compounded products that they  
16 were shipping into interstate commerce?

17 MR. CHALOS: Object to the form. Time frame.

18 THE WITNESS: So you're -- you've misstated the  
19 record.

20 MR. GIDEON: Q. It's not a statement of  
21 the record, Dr. Kessler -- wait a minute -- it is a  
22 question that deserves an answer.

23 A. Right. So FDA cited in this policy, as you and  
24 I went through, right, that the agency will consider  
25 whether a pharmacy engages in any of the following acts.

1 And it lists 1 through 9.

2 You read me a statement that was a factual  
3 question, right, under discussion. You implied, in that  
4 question, or I understood, that one of the criteria was  
5 an inordinate amount of 1 through 9.

6 What I stated on number 1 was where I saw  
7 limited quantities had to do with limited quantities in  
8 relation to the amounts of drugs compounded after  
9 receiving valid prescriptions.

10 So again, the essential issue here is, I mean,  
11 are there prescriptions, right? And the amounts that  
12 you're compounding with regard to the amount of  
13 prescriptions you have, that's the issue here.

14 Q. Well, apparently the FDA disagrees, in 2002,  
15 because the FDA took the time to say that one of the  
16 factors that the FDA is going to look at is whether or  
17 not an entity is receiving and using large quantities of  
18 bulk drug substances to manufacture large quantities of  
19 unapproved drug products in advance of receiving a valid  
20 prescription for them?

21 A. Where are you reading from? You're reading  
22 from a sentence under Discussion.

23 In fact, if you -- to be correct, let's look  
24 under the Policy where it says: The agency will  
25 consider -- in determining whether to initiate such

1 action, the agency will consider nine factors. You and  
2 I talked about that.

3 And I don't see what you're reading as one of  
4 the factors that FDA said it would consider. Am I  
5 wrong?

6 Q. So from the standpoint of this self-proclaimed  
7 expert in drug regulation, volume by a compounder was  
8 irrelevant to the FDA?

9 MR. CHALOS: Object to the form.

10 MR. ARBITBLIT: Object to the form.

11 Argumentative.

12 THE WITNESS: So, again, I was confirmed by the  
13 United States Senate, appointed by one president,  
14 reconfirmed -- I mean, kept on by a second president,  
15 right? And I ran the agency for seven years.

16 So, again --

17 MR. GIDEON: Q. Is volume relevant or  
18 irrelevant?

19 A. I'm taking issue. You felt it necessary to  
20 talk about self-proclaimed.

21 Q. Yeah.

22 A. Right? You didn't need to do that. Okay?

23 Now let's talk about volume.

24 Q. Is volume relevant or not relevant?

25 A. I believe that volume is relevant. If you read

1       No. 1, okay? If you -- if you want to be precise and  
2 understand how this works, right, volume is relevant,  
3 right, as it relates to prescriptions, right? So you  
4 can only -- I mean, you can only compound, right, a  
5 very -- a very limited quantity without prescriptions.

6                  What is not answered in these is if you had  
7 prescriptions, can you compound, right, more than a  
8 limited quantity. If you -- certainly that's under this  
9 policy.

10                 Under the law, right, I didn't see, again,  
11 except as it related to the anticipation of  
12 prescriptions, any limitations on how much you can do  
13 under FDAMA. I saw there was a limitation of how much  
14 you could have on hand, right, in anticipation of  
15 prescriptions. That's where volume is key.

16                 Q. All right. So volume is relevant, but there  
17 are two factors: How much volume is generated based on  
18 patient-specific prescriptions, and how much volume is  
19 generated without patient-specific prescriptions?

20                 A. Well said.

21                 Q. Thank you. We agree on that.

22                 A. Thank you.

23                 Q. Let's turn to page 4, see if we can continue  
24 this process of agreement.

25                 Page 4, down at the bottom, under Regulatory

1       **Action Guidance.**

2           A. Yes, sir.

3           Q. We shouldn't have to read it but it does say:

4       District offices are encouraged to consult with state  
5       regulatory authorities to assure coherent application of  
6       this guidance to establishments that are operating  
7       outside of the traditional practice of pharmacy.

8           I've read that correctly, haven't I?

9           A. Yes, sir.

10          Q. And then the next paragraph tells us some of  
11       the remedies that are available if the FDA decides to  
12       take some action, correct?

13          A. Yes, sir.

14          Q. Warning letter was one available in 2002?

15          A. Yes.

16          Q. Seizure of product, correct?

17          A. Yes.

18          Q. When you were commissioner, wasn't there a  
19       seizure of orange juice that was being represented to be  
20       fresh but, in fact, was made from concentrate?

21          A. Yes. The United States marshals --

22          Q. Yes.

23          A. -- for economic adulteration pursuant to the  
24       act.

25          Q. Injunction, something we talked about earlier,

1      correct? A civil injunction to make somebody stop doing  
2      something?

3            A. Right.

4            Q. And prosecution. These last two require entry  
5      into the judicial system, correct?

6            A. Yes.

7            Q. All right.

8            A. But as -- I'm sorry.

9            Q. Now --

10          A. But some of those are not applicable, I mean,  
11      if you're a compounder. You and I can agree on that,  
12      right?

13          Q. Well, we'll see.

14          Now, were you shared -- did these folks tell  
15      you that in the summer -- excuse me -- in May of 2011,  
16      NECC had a cease and desist order issued against it by  
17      the state Board of Pharmacy in Colorado?

18          A. I think you saw the document. You read the  
19      document earlier into the record that I had pertaining  
20      to that.

21          Q. So you know that in May of 2011, the Colorado  
22      state Board of Pharmacy issued a cease and desist order  
23      against NECC?

24          A. That's correct.

25          Q. You also know that that cease and desist order

1 was sent to the New England District Office of the FDA?

2 A. I do know it was in receipt -- yes.

3 Q. You also know that the New England District  
4 Office of the FDA did not send that cease and desist  
5 order to the Massachusetts Board of Registration and  
6 Pharmacy, don't you?

7 A. I've read Dr. Hamburg's testimony on that. In  
8 fact, I have the exact language. Let me tell you what I  
9 know. Dr. Hamburg testified she wished there was better  
10 communication. The Massachusetts Board of Pharmacy said  
11 they became aware of it in the -- in 2012.

12 Q. '12?

13 A. Right. I think Dr. Smith testified to that, if  
14 my recollection is right.

15 Q. The interim commissioner, Lauren Smith, of the  
16 Massachusetts Board of Pharmacy?

17 A. She said the executive -- there was something I  
18 didn't quite understand. I have the testimony, let me  
19 just get it.

20 Q. You are free to do it if you wish, but I can  
21 tell you that the Penta deposition establishes as well  
22 that the Massachusetts Board of Registration and  
23 Pharmacy did not get the May 2011 cease and desist order  
24 until June or July of 2012.

25 A. I believe Dr. Hamburg -- and I want to check



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1 this -- FDA asked Colorado to share with Massachusetts  
2 Board of Pharmacy, but let's just get the actual  
3 testimony.

4 Q. So that you understand, though, my question is,  
5 do you know that when the New England District Office of  
6 the FDA got the cease and desist order in May of 2011,  
7 they did not send it on to the Massachusetts Board of  
8 Registration and Pharmacy?

9 MR. CHALOS: Object to the form.

10 THE WITNESS: Let me check so we're actually  
11 clear, and we can put this on the record, if you like.  
12 The answer is in Exhibit 1237 that you marked. Let me  
13 just see.

14 Let me just read you exactly what we -- what I  
15 know, and it's only based on what Dr. Hamburg and what  
16 Dr. Smith testified. You know, in retrospect -- this is  
17 Dr. Hamburg -- clearly I would have hoped that there  
18 would have been greater communication that speaks to the  
19 issue that was raised about ensuring the appropriate  
20 level --

21 (Reporter clarification.)

## 22 THE WITNESS: Sorry.

23 -- that speaks to the issue that was raised  
24 about ensuring the appropriate level of back-and-forth  
25 communication and coordination with our state partners.



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1 When this email was received, it was in the context of a  
2 violation of state pharmacy registration and licensure.  
3 And while there was an indication they had sent the  
4 product in the absence of patient-specific  
5 prescriptions, there was no indication of a safety or  
6 quality concern that was being raised.

7 So, you know, we really felt that it was, as I  
8 understand it, those kinds of issues are often handled  
9 state Board of Pharmacy to state Board of Pharmacy. We  
10 should have made sure that Massachusetts was aware.

11 But there's also other testimony --

12 MR. GIDEON: Q. You just read that to me.  
13 How does that answer the question I asked you?

14 A. Well, because I wasn't at FDA at the time.

15 Q. We know that.

16 A. Well --

17 Q. How does that answer the question I asked you,  
18 which was as an expert in this case, do you know whether  
19 FDA passed on to the New England -- excuse me,  
20 Massachusetts Board of Registration and Pharmacy the  
21 FDA's unquestioned receipt of a cease and desist order  
22 from Colorado against NECC issued in May of 2011?

23 A. And the answer, as I just told you that  
24 Dr. Hamburg testified, that she had wished there was  
25 better communication. There was not a product quality



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1 or safety issue.

2 And what I'm trying to determine, and there's  
3 other pages of testimony, whether -- that I thought I  
4 read where FDA said to the -- said to Colorado, share  
5 this with Massachusetts. That's -- again, this  
6 testimony is the extent of my knowledge.

7 Q. So how does it answer the question then?

8 A. It --

9 Q. It doesn't.

10 A. It tells -- well, she was asked about those  
11 questions. This is the record that I have.

12 Q. Well, let's look at it -- I assume it's the  
13 best you can do in answering my question of whether they  
14 did or didn't share the information? They, being the  
15 FDA with the --

16 A. Well --

17 Q. Excuse me.

18 -- the Massachusetts Board of Registration and  
19 Pharmacy?

20 MR. CHALOS: Object to the form.

21 THE WITNESS: Actually, there's more here.

22 This is Dr. Smith: Just to be clear, while the  
23 executive director of the Board of Pharmacy did receive  
24 notification from the Colorado Board of Pharmacy  
25 regarding the cease and desist, that was done in



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1     April -- done in April of 2011. We have not found any  
2 record that there was any communication from the  
3 Colorado Board at that time back in 2011.

4                 That's the testimony. That's what I can --  
5 that's what I have.

6     Q. Well, let's apply the compliance policy guide  
7 at page 4. If the New England District Office of FDA  
8 gets an email from the Colorado Board of Pharmacy that  
9 says we have issued a summary suspension, a cease and  
10 desist order of NECC for improper conduct here in our  
11 state, under the compliance policy guide, the district  
12 office there in Boston should have shared that report  
13 with the Board of Registration and Pharmacy in the state  
14 of Massachusetts, correct?

15                 MR. CHALOS: Object to the form.

16                 THE WITNESS: Or tell Colorado to send it.

17                 I mean, the -- I'm certain -- let me just get  
18 the exact language. Certainly if this --

19                 MR. GIDEON: Q. I am referring to  
20 regulatory action guidance.

21                 A. This says they are encouraged to consult with  
22 state regulatory authorities to assure coherent  
23 application.

24                 I mean, again, we have to look at the record  
25 whether Colorado was asked to send this to

1 Massachusetts. This was, again, at this time what is --  
2 what I think is the most important. If there was a  
3 product safety or significant -- if the product was  
4 contaminated, right, that clearly should have been the  
5 number one issue for FDA. And if there was evidence of  
6 that, even as an old drug, the agency should have done  
7 something.

8 Q. Right. And in addition to that, though, if the  
9 report from Colorado makes it clear that NECC is selling  
10 product in the state of Colorado without  
11 patient-specific prescriptions, raises the issue of  
12 whether NECC should be registered as a manufacturer with  
13 the FDA, doesn't it?

14 A. It certainly raises that question. Law was --  
15 the law was very confused at this time. And what you  
16 see, whether we like it or not, that confusion,  
17 certainly post Gonzalez and Ukease, led to this sort of  
18 very gray area.

19 MR. GIDEON: Give me number 20.

20 THE WITNESS: Can I ask how much time we have  
21 left?

22 THE VIDEOGRAPHER: Five hours and 53 minutes on  
23 the record.

24 THE WITNESS: Five hours and 53 minutes.

25 MR. GIDEON: We've got 5 hours and 53 minutes



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1 left, in response to your question.

2 THE WITNESS: Thank you. I look forward to  
3 this.

4 MR. GIDEON: 1257.

5 (Whereupon, Exhibit 1257 was marked for  
6 identification.)

7 MR. ARBITBLIT: In other words, an hour and  
8 seven minutes left.

9 THE WITNESS: Where would you like to go for  
10 dinner in San Francisco?

11 MR. GIDEON: What's the name of that old  
12 seafood place?

13 MS. WEETER: Tadich.

14 MR. GIDEON: Tadich. Great food.

15 THE WITNESS: Let's talk before you go to  
16 dinner.

17 MR. GIDEON: Okay.

18 Q. All right. I've handed you an FDA alert to  
19 healthcare professionals.

20 A. Yes.

21 Q. This deals with Cape Apothecary, Inc. in  
22 Anapolis, Maryland, issued November 15th, 2015.

23 A. Yes.

24 Q. One of the things that's mentioned at the -- in  
25 subsection -- well, the subsection entitled regulatory

1 action guidance that we talked about a few moments ago,  
2 was FDA --

3 A. Regulatory action guidance. In this  
4 document --

5 Q. No, no, no. Compliance policy guide.

6 A. Yes, sir.

7 Q. We talked about it a moment ago. FDA initiated  
8 regulatory action may include issuing a warning letter.

9 Is the document in front of you right now an  
10 example of a warning letter?

11 A. No.

12 Q. Tell me how the document in front of you right  
13 now is different than a warning letter?

14 A. A warning letter, as that term is used, is a --  
15 there will be an addressee company, and it will be  
16 labeled -- warning label usually in bold and underlined.

17 Q. Okay.

18 A. It will be identified as such.

19 Q. So what was -- what was this type of document  
20 that's in front of you called in the FDA lexicon?  
21 Public alert? Informational? What was the term?

22 A. These are probably drug safety -- this was some  
23 drug alert and statement.

24 Q. Well, this alert tells the public don't use  
25 products from this company, right?

1           A. Dated when?

2           Q. I just told you. 11/15/2015.

3           A. After we've had probably the worst national  
4 crisis since Sulfanilamide, right?

5           Q. Now, was this -- was this capacity to alert the  
6 public something that only began November -- September  
7 26, 2012, or was this capacity something FDA had  
8 beforehand?

9           MR. ARBITBLIT: Object to the form.

10          THE WITNESS: The capacity?

11          MR. GIDEON: Q. The power, the authority,  
12 to issue this kind of document, did that exist only  
13 after September 26th, 2012, or was it something that  
14 the FDA could have done in 2010, 2011, 2012?

15          MR. ARBITBLIT: Object to form.

16          THE WITNESS: So certainly FDA could have,  
17 under all -- all interpretations of law, had FDA found  
18 samples that were contaminated, right, if you had a drug  
19 sample, as they did back in 2002, I believe, if you have  
20 a drug sample that's contaminated, FDA -- and/or that  
21 that sample may be injurious to health, FDA can act.

22          You have to have a sample, right, and -- of  
23 drug product, right? Some type of contamination,  
24 filthy, putrid, under the old drug provisions. If they  
25 had that, they could have -- they could have clearly



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1       acted under any interpretation of the law and should  
2       have.

3           Q. Okay. Now, you are not suggesting that the  
4       Western States case took away the authority of the FDA  
5       to act with respect to contaminated, adulterated, putrid  
6       product made by any manufacturer?

7           A. That's correct. That's correct, but you would  
8       have to have a drug sample -- I mean, you would have to  
9       have that in the drug sample, you would have to have  
10       laboratory confirmation, right? You'd have to show that  
11       that could be injurious to health, then you can go into  
12       a court and you can act.

13          Q. Okay.

14           Give me 21.

15           (Whereupon, Exhibit 1258 was marked for  
16       identification.)

17           MR. GIDEON: The exhibit number is on the back  
18       of the first page. 1258.

19           MR. ARBITBLIT: Counsel, just for the record,  
20       if you altered the original of this by putting certain  
21       items in bold --

22           MS. WEEETER: Here's the original.

23           MR. ARBITBLIT: Well, let's have that marked as  
24       well as the accompanying exhibit.

25           MR. GIDEON: I don't follow the objection.

1                   **MR. ARBITBLIT:** Well, this -- you've altered an  
2 original document by highlighting the matters that you  
3 feel are important, and I think it would be appropriate  
4 for the record to reflect the original of this document  
5 in addition to the version that you would like to  
6 question the witness upon.

7                   **MR. GIDEON:** Well, actually, I don't think  
8 you're right. I don't think you're right. I'll tell  
9 you what the methodology is.

10                  The normal nonbolded print you will find at  
11 FDA E00424316, 317 and 318. Okay? What we have done is  
12 interspersed into this document, based on the subsequent  
13 production by the Food and Drug Administration, other  
14 documents with separate FDA numbers. And they are  
15 bolded only to reflect that they are not part of the  
16 original.

17                  **MR. ARBITBLIT:** Thank you.

18                  **MR. GIDEON:** So that's the methodology.

19                  **MR. ARBITBLIT:** Thank you for clarifying that.

20                  **MR. GIDEON:** And if you want to, we can mark  
21 FDA 424316, 317 and 318. I have no objections to that.  
22 But it's actually not me emphasizing or changing  
23 something for the purposes of emphasizing it.

24                  **MR. ARBITBLIT:** Fair enough. I appreciate the  
25 clarification.

1                   MR. GIDEON: Okay.

2                   MS. WEETER: I'll also add that we have the  
3 supporting documents for the subsequently produced ones  
4 that are highlighted in bold.

5                   MR. GIDEON: So you don't have to object under  
6 Rule 106 about completeness. We have all of the  
7 underlying documents as well here, and he is free to  
8 look at them.

9                   Q. What I'm going to suggest is that you take a  
10 look at this document for a few moments. You will find  
11 that it is chronological. The regular print was  
12 produced by your former employer, the FDA, in its  
13 Production of Documents, as I mentioned to you, with the  
14 FDA numbers.

15                  A. Okay.

16                  Q. Three numbers. And then the additions have  
17 separate FDA production numbers because they have made  
18 productions to us on what they referred to as a rolling  
19 basis. Okay?

20                  A. I'm -- I was confused. Was this originally --  
21 you are saying this was done by FDA.

22                  MS. WEETER: It was originally produced by FDA.

23                  THE WITNESS: Produced. That's not my  
24 question. What is the typed by the house committee or  
25 what is the typed by FDA?



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1                   **MR. GIDEON:** Q. Prepared by FDA. Produced  
2 by FDA. We can't go any further than that. I don't  
3 know.

4                   A. So I --

5                   Q. Never had an opportunity to ask a single  
6 question of anybody with FDA to ask them.

7                   A. I think this -- if you go online, this is house  
8 committee work. But again, let's --

9                   Q. Well, you may be ahead of the ball and you are  
10 more familiar with it.

11                  A. That's fine.

12                  Q. But I don't want to start asking you questions  
13 on it until you've had at least an opportunity to  
14 acquaint yourself with some of these sections.

15                  I'm going to take five minutes and go to the  
16 bathroom while you're taking a look at it, since we got  
17 5 hours and 57 minutes left to go.

18                  THE WITNESS: Look forward to it. All five  
19 hours.

20                  MR. ARBITBLIT: Off the record.

21                  THE VIDEOGRAPHER: This is the end of disc  
22 No. 4, volume 1.

23                  THE WITNESS: Going off the record?

24                  THE VIDEOGRAPHER: We're going off the record  
25 at 4:02 p.m.

(Recess taken from 4:02 PM to 4:15 PM)

THE VIDEOGRAPHER: This is the beginning of disc No. 5, volume 1.

We are back on the record at 4:15 p.m. You may proceed.

MR. ARBITBLIT: I have a brief objection to Exhibit 1258 which includes excerpts taken by counsel for the defendants interspersed and interlineated with previous documents.

And it's burdensome, during the deposition, to have to review the original documents to see what defense counsel has chosen to highlight as opposed to what may be necessary to complete the record. That's my objection.

**MR. GIDEON:** Ready?

THE WITNESS: I am. And if I can also add something, if I may. You asked me to look at this.

MR. ARBITBLIT: You may not. You may wait for a question.

THE WITNESS: No, I'm going to put something on the record, Don. I apologize. Because I think this is important.

You asked me to read this. And again,  
pertaining to the earlier conversation, if you look  
at -- there's an entry on --



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1                   MR. GIDEON: Q. The lawyer over here just  
2 told you you couldn't make this addition. Are you  
3 not going to follow his advice?

4                   A. I am not going to follow his advice.

5                   MR. ARBITBLIT: There's a question that counsel  
6 has asked you you can now answer.

7                   THE WITNESS: I'm now going to answer.

8                   MR. GIDEON: Q. You are not going to  
9 follow the lawyer's advice?

10                  A. No, I'm not.

11                  Q. Is that the question?

12                  MR. ARBITBLIT: Yes, that was your question.

13                  MR. GIDEON: And I got an answer to that. Now  
14 I'm going to ask my next question.

15                  THE WITNESS: This is important, sir, I'm not  
16 being flip at all. May I do this, please?

17                  MR. GIDEON: I haven't --

18                  MR. ARBITBLIT: You may.

19                  MR. GIDEON: I haven't asked you a question --

20                  THE WITNESS: You --

21                  MR. GIDEON: -- and this doesn't count against  
22 my time.

23                  If you wish to make a statement, I guess  
24 there's no way I can stop you right now.

25                  THE WITNESS: I think this document is in

1 violation of the agreement that you have with the  
2 Department of Justice and I would ask you to check with  
3 them before you ask any questions.

4 MR. GIDEON: Q. Well, I don't. And I'm  
5 not going to be objecting to my own questions on  
6 behalf of the Department of Justice. I am going to  
7 ask you questions about the facts that are shown in  
8 the exhibit. The facts come from documents produced  
9 by the Food and Drug Administration and specific  
10 documents in a rolling production. So --

11 A. This --

12 Q. -- I will begin by asking --

13 A. This document --

14 Q. I --

15 A. Let me finish, sir, please.

16 Q. No, no. I was in the middle of a sentence,  
17 Dr. Kessler, and you --

18 A. You didn't let me finish --

19 Q. -- do not have the prerogative to interrupt  
20 someone else who is speaking.

21 A. I respect that --

22 Q. That is not your prerogative.

23 A. But, please, there's a serious issue here.

24 (Reporter requests one speaker at a time.)

25 THE WITNESS: You are not letting me put that



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1 on the record.

2 MR. GIDEON: She asked you to be quiet and you  
3 didn't.

4 MR. ARBITBLIT: Counsel, she asked you both  
5 equally.

6 MR. GIDEON: She's looking right at Dr. Kessler  
7 who just keeps talking no matter what anybody says.

8 MR. ARBITBLIT: That's uncalled for.

9 MR. GIDEON: Q. Now, one thing, in the  
10 limited amount of time you and I have together  
11 today, but I do think there will be another  
12 opportunity, is for you and I to please speak one at  
13 a time so that we can both be kind to the court  
14 reporter. Will you agree to do that?

15 A. I'd be happy to do that.

16 Q. All right. Now, I can't stop you from making a  
17 speech about the documents, so will you please do it and  
18 get it over with so I can ask a question.

19 A. You have added to this document on the last  
20 page information about the office of the chief counsel  
21 at FDA whose -- again, I don't want to characterize it  
22 as legal advice, but you've been advised not to go near  
23 attorney-client privilege.

24 I think when you are talking about the office  
25 of the chief counsel is not doing something, I'll leave

1       others to decide whether that's attorney-client. That's  
2       not my job. But I do think you are very close to the  
3       line, and I would certainly request that you not put me  
4       in a position, right, not to be respectful to the letter  
5       you received.

6                   So I think your -- that's being cited here.  
7       And again, I just think it's important -- I think you  
8       should be careful.

9                   Q. Well, Doctor, do you remember when you were in  
10      law school addressing attorney-client privilege? And do  
11      you recall being told that if you produce information  
12      that reflects the communications, it can be waived? Do  
13      you recall that?

14                  A. And please have that discussion with the  
15      Department of Justice, sir.

16                  Q. I'm not going to have this discussion with you  
17      any longer. Are you referring to the entry of July  
18      17th, 2012 from a document the FDA produced to us which  
19      said: Bruce Ota emailed Karen Archdeacon, quote, OCC at  
20      the moment is not doing anything with compounding  
21      pharmacies because of the recent losses in the  
22      southwest, end quote?

23                  Is that the one you are referring to?

24                  A. Yes. To me --

25                  Q. Do you know where we got the document?

1           A. I'm sure you got it from FDA. But clearly,  
2 that document -- statement that if that is not  
3 deliberative process, I don't know what is deliberative  
4 process.

5           Q. Okay. Well, let's talk about June 2007, the  
6 first page.

7           A. Okay.

8           Q. When did the MedWatch system take effect? What  
9 year?

10          A. I did MedWatch probably 1994, '5, something  
11 like that.

12          Q. You see in June of 2007 in the original  
13 produced by FDA, FDA receives a MedWatch report about a  
14 patient receiving an NECC-repackaged Avastin injection  
15 for macular degeneration, April 2007, developing a  
16 severe eye infection and needing emergency surgery.

17          Now, is that representative of the kind of  
18 information that FDA would need before they act to  
19 protect the public?

20          MR. CHALOS: Objection. Form.

21          THE WITNESS: You need a lot of information to  
22 protect the public. As I understand that case -- and  
23 again, I can give you the records -- certainly on some  
24 of the Avastin cases that I looked into the adverse  
25 events, there was a diagnosis of sterile

1 endo-ophthalmalitis (sic).

2 MR. GIDEON: Q. Endophthalmitis?

3 A. Yes. Endo-ophthalmalitis (sic). And as I  
4 understand it, you look at those records, I did not see,  
5 again, I mean FDA is questioning whether it's a  
6 compounder or a manufacturer, we know. But those came  
7 in, but I don't see any samples that were positive that  
8 I'm aware of with regard to that.

9 Q. Is it because FDA didn't take the time to ask  
10 for samples from the Avastin injection for macular  
11 degeneration that NECC made? Is that why there are no  
12 samples?

13 A. I don't know, but I'm not aware of any samples.  
14 I don't know, but the record does not show any positive  
15 samples there. And I guess there were, from that -- I  
16 think it was Genentech, they're talking -- there were  
17 documents about 40 to 50 patients who got that lot, and  
18 that there were no issues. I just don't see any samples  
19 that were positive. I don't know why there was not --  
20 whether there was or was not samples. I just am not  
21 privy to that.

22 Q. Well, accepted regulatory oversight would have  
23 required FDA, when they received a report on MedWatch  
24 that a patient had developed a severe eye infection  
25 requiring emergency surgery, to at least attempt to



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1 obtain samples from that Avastin packaging, wouldn't it?

2 MR. CHALOS: Object to the form.

3 THE WITNESS: No.

4 MR. GIDEON: Q. No?

5 A. But again, FDA -- FDA gets thousands and  
6 thousands of adverse events. And again, I don't see a  
7 full record of what FDA did here. So I'm just not privy  
8 to that. I just can't opine.

9 Q. Do you know if FDA did anything at all?

10 A. Dr. Miller says it prompted an inspection. But  
11 the documents that I see don't support that these  
12 adverse events prompted the inspection. But, again, I  
13 can't quite connect the dots.

14 Q. Well, you'll be able to connect the dots when  
15 you look at this. There wasn't another inspection of  
16 NECC by FDA from 2003 until 2012, was there?

17 MR. ARBITBLIT: Object to form.

18 THE WITNESS: So there was follow-up. There  
19 was -- there were no issues, as I understand it, between  
20 that recall and about 2007, as far as adverse reactions.

21 Beginning in 2007, I see a number of incidents,  
22 right, beginning in 2007. You have these MedWatch  
23 reports. There was an issue of a liposuction. There  
24 was an issue of klebsiella. There was an issue of  
25 phosphatidylcholine. And what I see is FDA going to



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1 inspect and try to determine, certainly on the  
2 liposuction, on the phosphatidylcholine, on the  
3 klebsiella, and none of that, to my knowledge, showed  
4 any positive samples or gave -- as I see the record.  
5 And basically FDA, in a number of these cases subsequent  
6 to 2007 where FDA's doing stuff, FDA is going to look at  
7 the issue.

8 I don't have the record on Avastin, but in  
9 other cases, FDA is looking at the record and trying to  
10 determine the basis.

11 MR. GIDEON: Q. What question are you  
12 answering? Because you've been talking for so long,  
13 I've forgotten if I even asked you a question.

14 A. You asked me what FDA did.

15 MR. CHALOS: Object to the commentary.

16 MR. GIDEON: Q. No, I asked you whether or  
17 not they had done an inspection between 2003 and  
18 2012, an inspection of NECC, and then you started  
19 talking. You have not yet answered whether FDA put  
20 a boot in the door at NECC between 2003 and 2012,  
21 and that's what I want to know.

22 A. FDA did not step foot in NECC. FDA did put a  
23 boot in a number of complaints that were allegedly  
24 related to NECC.

25 Q. In 2003?

1           A. No. FDA investigated things in 2008, April,  
2 October, as you see on -- I mean, there were certain --

3           Q. They did an inspection?

4           A. No. What they did was they went after there  
5 was a report, for example, about phosphatidylcholine.

6 The --

7           Q. We'll get to that.

8           A. -- LA district office. You can go through  
9 that. So FDA went through and tried to determine the  
10 cause, right?

11          Q. But let's take it step by step.

12          A. Please.

13          Q. From 2003, and you will recall we talked about  
14 a recall of methylprednisolone acetate preservative  
15 free, and betamethasone, the two that led to the  
16 significant recalls in the 26 states.

17          A. Yes.

18          Q. After that occurred, that was the last time any  
19 person employed by the Food and Drug Administration set  
20 foot at any NECC until after the fungal meningitis  
21 catastrophe; isn't that right?

22          A. I think that's correct.

23          Q. Okay.

24          A. But that's because -- just so you -- between  
25 2002 and 2007, there weren't any adverse event reports

1       that I saw.

2           Q. That's why we're doing this. Now we've just  
3       talked about --

4           MR. ARBITBLIT: Object to that.

5           MR. GIDEON: Q. -- June of 2007 with the  
6       man who had emergency surgery and had a severe eye  
7       infection. Look at the next entry --

8           A. Just give me what patient that was, because I  
9       have three. Just give me -- you can give me the  
10      MedWatch report.

11          Q. The patient's name?

12          A. Just give me the FDA documents. I have three  
13      reports of Avastin. If we're going to talk about them,  
14      just give me the MedWatch reports.

15          Q. We're looking at your blotter. You have three  
16      reports of patient sickness or injury connected with  
17      Avastin repackaging?

18          A. I have three MedWatch reports concerning  
19      Avastin, but I don't have --

20          Q. What's the date on those three reports that you  
21      recorded?

22          A. I have somewhere around 2007.

23          Q. 2007. Did you write down the FDA document  
24      numbers as you prepared that blotter?

25          A. Yes, I do.



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1 Q. Okay. Well, then we know the FDA document  
2 numbers.

3 A. But if you want to discuss the case --

4 Q. I want to discuss the exhibit that's in front  
5 of you.

6 A. No, no. But I can't discuss a case without  
7 giving me -- you're giving me a house report that is a  
8 one-page -- one sentence about a case. If you want to  
9 show me about a case, please show me the record.

10 Q. Well, I'm going to ask you questions. I will  
11 expect you to answer them. December of 2007, FDA  
12 receives a call from a physician who had administered  
13 epidural injections of betamethasone to numerous  
14 patients who then experienced severe flu-like symptoms?

15 A. Uh-huh.

16 Q. They find several vials made between August and  
17 October of '07 that are discolored and contained  
18 particles. What did FDA do in December of 2007 to  
19 protect the public from NECC?

20 A. You need to give me the -- that inspection  
21 report and that file.

22 Q. You don't know?

23 A. Well, again, you are asking me specifically in  
24 December 2007. Dr. Miller -- I mean, unless this is --  
25 didn't -- no one has raised this case that I've seen in

1 Dr. Miller's report, or Mr. Bradshaw's report, with this  
2 date. So if you want to give me more information, just  
3 give me the file on this case.

4 MR. ARBITBLIT: So for completeness, Counsel,  
5 I'd like to read from one of the documents that your  
6 associate provided pertaining to this very episode of  
7 betamethasone. I'm reading from FDA E00426108, and also  
8 marked as NECC\_FDA 02598, lab class 1, no bacterial  
9 endotoxins detected in 1 through 5 subcomposites  
10 pertaining to the betamethasone episode that you are  
11 referring to.

12 MR. GIDEON: Q. Now, I want you to read  
13 the whole thing to make sure it's complete, but I  
14 don't want to waste time doing it. Is there any  
15 reflection here that FDA -- and I assume you are  
16 referring to the Bruce Ota compliance officer  
17 document. Is there any indication here that there  
18 was any effort to find whether there were  
19 patient-specific prescriptions?

20 You've obviously spent some time reading it; is  
21 there any reference to that in the document?

22 MR. ARBITBLIT: Counsel, you are entitled to  
23 read anything else you feel is necessary from the  
24 document.

25 MR. GIDEON: Well, then we need to exhibit --

1                   MR. ARBITBLIT: You are not entitled to ask me  
2 questions.

3                   MR. GIDEON: We need to make that an exhibit,  
4 then, right now.

5                   MR. ARBITBLIT: That's fine.

6                   MR. GIDEON: The next exhibit will be  
7 FDA 426108 to 426109. And you will see that there is  
8 nothing in here about even asking if there are  
9 patient-specific prescriptions.

10                  MR. CHALOS: Objection to the commentary.  
11 That's not a question.

12                  MR. GIDEON: Right. Trying to save time.

13                  MR. CHALOS: I'm not sure why you are taking  
14 time making speeches, frankly.

15                  MR. GIDEON: Got to do it. Got to do it.

16                  (Whereupon, Exhibit 1259 was marked for  
17 identification.)

18                  MR. GIDEON: Q. Now, the same document  
19 that the gentleman just a moment ago brought up at  
20 FDA 426109, I'm going to hand this to you, Doctor.  
21 Bruce Ota, compliance officer to the New England  
22 district, comments in his email to Samia Nasr,  
23 quote: This appears to be a new drug --  
24 Dr. Kessler -- this appears to be a new drug this  
25 company is compounding.



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1                   Now, as of December of 2007, were compounders  
2 permitted to make new drugs and skip registration with  
3 the FDA?

4                   MR. ARBITBLIT: Object to form.

5                   THE WITNESS: I don't understand your question.

6                   MR. GIDEON: Q. Could a compounder make  
7 new drugs whenever they wished and in whatever  
8 volumes they wished?

9                   A. The new drug is a -- is a provision of the act.  
10 I'm not sure, again --

11                  Q. Could a compounder make a new drug and sell it  
12 in interstate commerce without seeking approval from the  
13 FDA in advance?

14                  A. This is -- let's define new drug, as this is --  
15 in this case, this is a -- this is a -- a copy of an  
16 approved drug. This is a different drug.

17                  If this is a different drug, not a copy,  
18 essentially not a copy, right, you -- I mean, your  
19 question -- I mean, is it --

20                  Q. It's not my question, it's the comment by Bruce  
21 Ota. If Bruce Ota with the FDA is right, did NECC have  
22 the prerogative to make new drugs and sell them in  
23 interstate commerce if they wished to do so?

24                  A. Either you are a compounder, right? And a  
25 compounder -- if you are under FDAMA, if that was the

1 law, or you are exempt from new drugs. So you can't be  
2 a compounder and be subject to the new drug provisions,  
3 right?

4 Now let me look and see what the actual product  
5 is that's being sold here, and maybe that will shed  
6 light on what Mr. Ota is saying, right?

7 So this is New Orleans. This is actually --  
8 hold on a second. Okay. So this doesn't -- I  
9 apologize. You gave me this case in December of 2007.  
10 This is April 2008.

11 Q. Well, I didn't bring this up. Another lawyer  
12 in this room brought it up, so I thought I'd ask you  
13 about it.

14 A. But this document doesn't -- this is dated  
15 wrong. Because the issue, I mean, again, that I'm aware  
16 of --

17 Q. Could you please answer the question, just once  
18 today?

19 A. Sir --

20 MR. CHALOS: Objection.

21 MR. GIDEON: Q. One time, please.

22 MR. CHALOS: Objection to the commentary.

23 MR. GIDEON: Q. Just one time, can you  
24 answer the question directly.

25 A. I don't know what case this is referring to.

1 You represented this case --

2 Q. I didn't represent anything.

3 A. This is represented as being December 2007. I  
4 said I did not know what it is. I'm looking at this,  
5 and this is April of 2000 -- May of 2008 -- April, May  
6 of 2008. I certainly know what this case is about.

7 Q. Okay. Well, then, without all the windup,  
8 you've got the email in front of you, just tell us,  
9 since one of the FDA employees says it appears that NECC  
10 is making a new drug, were they permitted to do so  
11 without approval from the FDA? It's a really simple  
12 question.

13 A. So if someone could pull for me  
14 NEC\_FDA 05989-992.

15 Q. Do you have it?

16 A. I may. I have to find it. But if someone  
17 could -- so I don't have to -- it's late. If someone  
18 could help me find that document -- that document,  
19 please.

20 Q. How is that document going to help you answer  
21 my question about new drug?

22 A. Because my notes here says FDA says compounding  
23 with regard to the April 2008 case. You want to know  
24 whether this is new drug and not compounding. I need to  
25 see the FDA documents. Please give them to me that

1 relate to this case.

2 Q. And you don't have them?

3 A. I'd be happy to get them.

4 Q. Pull them up.

5 A. Okay.

6 Q. You got to have them to answer a point blank  
7 question, pull them up.

8 A. Okay. I will be happy to -- if someone  
9 could -- I just need the FDA FOI, because my folder  
10 is -- or I have to go find my thumbnail drive. I don't  
11 have -- I just need help on FDA 05989-992. And  
12 NEC\_FDA 06094-95. If someone could help me pull those  
13 documents up, happy to discuss this case.

14 Q. Go ahead. You've had them at some point.

15 A. I have a thumb drive.

16 Q. You are the best person to find them.

17 A. Well, I'd be happy. I have to find my thumb  
18 drive because it's not on the hard drive, as I told you  
19 earlier.

20 Q. Can you, slower, this time, dictate the FDA and  
21 NECC document numbers, please.

22 A. Sure. Happy to do that.

23 Q. While you're --

24 A. I'll look. So the documents I have -- if this  
25 relates -- if this relates --



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1           Q. Just give us the numbers.

2           A. Assuming this relates to the New Orleans case,  
3 right, I would appreciate seeing NECC\_FDA 06094-5 and  
4 NECC\_FDA 05989-992. Okay?

5           Q. Okay.

6           A. If someone could help me find those documents,  
7 I would appreciate it.

8           Q. We'll see who gets to it most quickly. If you  
9 can pull your thumb drive and we can see if we can pull  
10 them off our database.

11          A. Thank you very much. Here's my thumb drive.

12          MR. GIDEON: Let's see who is quickest. Feel  
13 some pressure, Kaycee?

14          (Inaudible discussion off the record.)

15          MS. WEETER: Got it.

16          MR. ARBITBLIT: All right, Kaycee.

17          MR. GIDEON: Is there any way we can put the  
18 document up on a screen in here, Don? Do we have the  
19 ability to transfer the document to a screen or can  
20 you --

21          MR. ARBITBLIT: You are asking the wrong guy.  
22 I'm such a -- I suggest that --

23          MR. CHALOS: I've asked for somebody to bring  
24 up some copies of those documents. So if you guys want  
25 to talk about something else in the meantime, we can



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1 come back to that when we get the documents.

2 MR. GIDEON: He says he can't answer the  
3 question without looking at the document.

4 MR. CHALOS: Maybe we can ask a different  
5 question.

6 THE WITNESS: I have the document, so I can  
7 pull it up here. Give me a second. I'm not as quick.

8 MR. GIDEON: Q. The first document is  
9 another email from Bruce Ota to Samia. It says:  
10 Below is the original email I sent to you. The  
11 consumer complaint number was made on 12/7/07 to the  
12 New Orleans district office. The collection report  
13 states the expiration date for sample X number is  
14 2/23/08. The manufacturer -- the manufacturer is  
15 New England Compounding Center, which they received  
16 a compounding WL, warning letter, that the center  
17 drafted and we sent. Do we want to do anything.

18 That's -- what's the document number on that?

19 MS. WEEETER: This is NECC\_FDA 06094.

20 MR. GIDEON: Okay.

21 THE WITNESS: Then it's 95, right?

22 MS. WEEETER: There's two.

23 MR. GIDEON: Why don't you read him the next  
24 one so he can hear that.

25 THE WITNESS: Thanks.



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1 MS. WEETER: The next email says --

2 MR. GIDEON: What's the date?

3 MS. WEETER: April 1st, 2008 from Bruce Ota to  
4 Samia Nasr.

5 Samia, I just received the attached worksheet  
6 for sample 426119. It appears the New Orleans office  
7 received a complaint from a Dr. blank -- it's  
8 redacted -- a pain specialist that treats fibromyalgia  
9 patients.

10 I believe this is the same information that's  
11 on this previously discussed document that you have in  
12 front of you that we just introduced.

13 THE WITNESS: That's Bates number ending in 95?

14 MS. WEETER: Yes, sir. It's the same. Oh,  
15 that was 94, excuse me.

16 THE WITNESS: And then 95?

17 MS. WEETER: Here's 95. 95 is the same  
18 information that you see on -- what was that last  
19 exhibit that was marked, 1259?

20 MR. GIDEON: You've got it.

21 THE WITNESS: Ask then one more.

22 MS. WEETER: It's the same email from Bruce Ota  
23 that references it was a new drug being compounded.

24 THE WITNESS: Could you pull up --

25 MS. WEETER: And then below that is an email



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1 from Mutahar Shamsi on April 1st, 2008, to Bruce Ota  
2 that says: Could you look at this please, it is from  
3 New England Compounding. It was classified as an LC2.

4 And that was his forwarding of the complaint  
5 from the New Orleans district office.

6 MR. GIDEON: Okay.

7 THE WITNESS: Could you do me a favor and pull  
8 up 05 --

9 (Reporter clarification.)

10 THE WITNESS: 05989.

11 MS. WEEETER: 05989.

12 THE WITNESS: That's what I have. To 992.

13 MR. GIDEON: These are FDA documents?

14 THE WITNESS: Yes.

15 MR. ARBITBLIT: It's the NECC\_FDA.

16 MR. GIDEON: Okay. If it's too long we can  
17 spin it around and look at it.

18 MS. WEEETER: Almost there.

19 THE WITNESS: I have this in a 74-page thing.  
20 Do you know what page it is? Part of a 74-page PDF.

21 MS. WEEETER: It's page 52 of 74.

22 THE WITNESS: Let me pull it up. At least I  
23 know what page it was. Fifty what?

24 MS. WEEETER: Fifty-two of 74.

25 MR. GIDEON: With lots of redactions.



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1 MS. WEEETER: There are lots of redactions.

2 THE WITNESS: So page 52. Change -- looks like  
3 I zoomed around. Sorry. So I can read it.

4 Yeah, so --

5 MR. GIDEON: Q. Are we there yet?

6 A. There's a considerable amount of material about  
7 this doctor that FDA is asking about. I think FDA --  
8 the doc apparently is still using this despite the  
9 discoloration. He's writing articles about this drug to  
10 use it, I guess.

11 Q. Now, remember what I wanted to know about was  
12 if, as the FDA said, this appeared to be a new drug, did  
13 the FDA have the responsibility to take some action?

14 MR. ARBITBLIT: Object to the form.

15 THE WITNESS: Hold on a second.

16 You can see that there's considerable  
17 investigation here of this doctor.

18 MR. GIDEON: Q. That's not responsive.

19 A. I understand.

20 Q. And I object to it. It's not responsive.

21 A. Okay.

22 Q. There's a pending question. Did FDA have an  
23 obligation to take some action if they thought, as Bruce  
24 Ota communicated, that NECC was making a new drug and  
25 selling it in interstate commerce?

1 MR. ARBITBLIT: Object to form.

2 MR. GIDEON: Q. Simple question.

3 MR. ARBITBLIT: Object to form.

4 THE WITNESS: Depends what a general counsel of  
5 the agency thought the law was. And as you've seen,  
6 there is questions about that.

7 MR. GIDEON: Q. Have you seen a single  
8 document where this issue on a product made in  
9 Massachusetts causing injury in New Orleans was ever  
10 presented to the general counsel's office for  
11 action?

12 A. And that's what -- that's what I raised my  
13 concern about. You see that certainly --

14 Q. Talking about April of 2008.

15 A. Right. But you see Ota in 2009, in February --  
16 and again I'm not privy to exactly what the -- I mean,  
17 all the FDA documents, right? I'm sorry. Let me just  
18 get --

19 Q. I don't see anything about general counsel in  
20 2009.

21 A. You certainly see general counsel's position in  
22 2012. That's what we have.

23 Q. That's four years later, Doctor.

24 A. I understand. But as you -- I mean, as I've  
25 testified before, you know after Ukesse, after 2008, I

1 mean, the agency was -- there was probably difference in  
2 opinion within the agency.

3 Q. Okay. What's your view, as the expert on  
4 regulation of drugs if, in fact, NECC was making a new  
5 drug that they made in Massachusetts caused injury in  
6 New Orleans, did the FDA have the responsibility to the  
7 public to take some action?

8 MR. ARBITBLIT: Object to form. Assumes facts  
9 not in evidence.

10 THE WITNESS: If it was viewed as a compounding  
11 pharmacy, FDA would only be allowed to do that by -- if  
12 it found samples that were contaminated. Then it would  
13 be allowed to do that, right?

14 MR. GIDEON: Q. Did FDA find samples that  
15 were contaminated?

16 A. I don't -- certainly there was no  
17 contamination. In this particular instance, there was  
18 decolorized vials. But there was no evidence of  
19 contamination that I have seen. That's why -- if you  
20 look at the record.

21 Q. There was a report that there was particulate  
22 matter in the vials; isn't that correct?

23 A. Yes.

24 Q. Okay.

25 A. I -- but that's not contamination, necessarily.

1           Q. The requirement not to sell adulterated product  
2       in interstate commerce isn't just limited to something  
3       that is contaminated with the biological origin, is it?

4           A. It was basically decomposed, filthy, putrid,  
5       because this was the old drug act.

6           Q. Sure.

7           A. And it may result in injury. Just because  
8       something is decolorized or particularized doesn't  
9       mean -- it depends whether there was something that  
10      could harm somebody in there. Bottom line is there  
11      something in there, is there growth. That's what you  
12      would specifically want, or other forms of  
13      contamination.

14          Q. So given the fact that that's that important,  
15       if FDA received a report that there's been patient  
16       injury from a product made by a compounder, first thing  
17       they should do is secure the product and test it to see  
18       if there is biological contamination within the vials?

19           MR. ARBITBLIT: Objection. I've already read  
20       the record. That's exactly what they did, Counsel. So  
21       it's misleading to keep questioning him about something  
22       they did.

23           MR. GIDEON: We need to establish some  
24       standards. We need to establish some standards from the  
25       expert on what needs to be done under given



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1       circumstances, not just rereading documents to us.

2       That's why I asked.

3                  THE WITNESS: If a doctor is making certain  
4       complaints, you would go into that doctor's office and  
5       you would look at the samples. You would -- and you'd  
6       interview the -- the -- you'd interview the doctor.

7                  There was a sample collected, it was 426119,  
8       and it was analyzed for endotoxin ID and potency. And  
9       the lab class 1, there was no -- I mean, I'm reading  
10      this. There was no bacterial endotoxins detected, as I  
11      read this, in one to five subcomposites, and it meets  
12      FDA requirement for assay -- assay and ID.

13                 So you have FDA testing here for endotoxin.  
14       And please note this product is 6 milligrams per mL of  
15      betamethasone. What -- and then they're talking about  
16      what they're measuring. And they're measuring.

17                 Q. Can you tell me what question you are  
18      answering?

19                 A. You asked me what the standard is, and I said  
20      it should be tested and, in fact, they tested the  
21      sample.

22                 Q. I see. Okay.

23                 Well, isn't there also a requirement that you  
24      get in and test soon enough so that the product doesn't  
25      get beyond its beyond use date before you test it?



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1       Surely you would agree with that?

2           A. I'm not sure I understand your question.

3           Q. Well, if you are going to test a product and  
4 determine if it's contaminated, one of the things you  
5 wish to do is test it before it reaches its product  
6 expiration date; isn't that correct?

7           MR. ARBITBLIT: Object to the form.

8           THE WITNESS: What you would do -- let's see  
9 where the sample was collected.

10           So it looks like this sample was -- I mean, if  
11 I read this, and it's not exact, this sample is probably  
12 one of the samples where the doctor was complaining  
13 about, although this record is not clear, right?

14           So you -- what you would want to do is to focus  
15 on the samples that were implicated by this doctor. If  
16 I say -- if this doctor is saying these samples are  
17 causing harm, you would want to test the implicated  
18 samples. I'm not sure I understand your question.

19           Q. But you want to test them promptly before they  
20 expire, correct?

21           A. Well, actually, you would probably -- you would  
22 have greater growth if you let it sit for a while if  
23 there was a problem.

24           Q. Yeah.

25           A. Right. So you would even see more of a

1 problem. So obviously, if someone is making a complaint  
2 that patients were injured, you would want to go in and  
3 test the sample. And that's what it seems to have done.

4 Q. Wouldn't you want to test the sample for fungi?

5 A. Well, the --

6 Q. Wouldn't you want to test the sample for fungi?

7 A. I'd be happy to let the -- depends on what the  
8 complaint was.

9 Q. We know that. We know what the complaint was.  
10 Under the circumstance, given the complaint, wouldn't  
11 you want to test for fungi?

12 A. I'll let the infectious disease experts testify  
13 exactly what they think it should be testified -- what  
14 it should be tested for.

15 Q. I'm talking about regulatory oversight.  
16 Wouldn't adequate regulatory oversight require testing  
17 not just for a bacterial contamination, but also fungi  
18 and viral contamination?

19 A. You certainly don't test for fungi all the  
20 time. It depends on what samples you have from the  
21 patient. So if you have positive cultures out of the  
22 patient that are fungi, then you would look for fungi,  
23 right? But infectious disease people can go through  
24 that, I think.

25 Q. But not you?

1           A. I'd be happy to discuss it if you want.

2           Q. Do you claim expertise in determining what  
3 kinds of tests must be run on product that has been  
4 seized for the purposes of determining if it's  
5 contaminated?

6           A. Yeah, I'd be happy to testify if you'd like.  
7 It depends on the context of the complaint. So if you  
8 see certain symptoms and you have certain cultures from  
9 patients, you want to be able to direct it, I mean,  
10 toward what the clinical symptoms. If the clinical  
11 symptoms are consistent with the fungal disorder, or if  
12 you have cultures, then you would certainly want to test  
13 for fungal.

14          Q. Okay. Now, look at the next entry, May of  
15 2008.

16          A. Will you give me the underlying documents on  
17 this one too, please.

18          Q. I'm going to ask the question.

19          A. Okay. But if you are --

20          Q. I'm going to ask you the questions.

21          A. Okay.

22          Q. The Ohio Board of Pharmacy reaches out to FDA  
23 again, this time regarding lidocaine injections stating,  
24 quote: Before the board issues a cease and desist to  
25 the Ameridose telling them to stop shipping manufactured



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1 products into Ohio under the guise of compounding. I  
2 wonder if you would verify for me whether or not this is  
3 a legitimately manufactured product that is made by an  
4 FDA-approved manufacturer, end quote.

5 In the event that an -- that a state Board of  
6 Pharmacy inquired of the FDA whether a company was FDA  
7 registered or not, didn't the compliance policy guide  
8 require an answer to that question?

9 A. The --

10 MR. CHALOS: Object to form.

11 THE WITNESS: I believe the compliance policy  
12 guide talked about encouraging cooperation. And --

13 MR. GIDEON: Q. Wasn't an answer required?

14 A. Required?

15 MR. CHALOS: Object to the form.

16 THE WITNESS: That's not what the policy -- it  
17 said encourages -- I mean, obviously if you asked me a  
18 question, I mean, if you are a state, you would expect,  
19 out of decent courtesy, to get an answer from that.

20 I don't have -- do you have the record of this,  
21 please? Do you have the underlying documents on this?

22 MR. GIDEON: Q. Whether we do or we don't,  
23 we're not going spend the time on it. I want to  
24 know whether or not the FDA had a responsibility to  
25 answer that question from the Ohio Board of

1       Pharmacy. Should be a simple answer.

2            MR. CHALOS: Object to form.

3            THE WITNESS: I'm not aware of a legal  
4 responsibility. As a matter of common courtesy, I would  
5 obviously expect that somebody should get back to them.  
6 Again, depending on the issue, right?

7            I mean, if there is a product quality or safety  
8 issue, that takes priority. I don't know what happened  
9 here. I don't have the record.

10          MR. GIDEON: Q. Well, we'll give you the  
11 next document which is FDA 426077 and 78, which  
12 pertains to June 27th, 2008.

13           (Whereupon, Exhibit 1260 was marked for  
14 identification.)

15          MR. GIDEON: You can read the exhibit number  
16 into the record.

17          THE REPORTER: What's the exhibit number?

18          MR. GIDEON: Q. The exhibit number,  
19 Dr. Kessler, on the front?

20          A. 1260.

21          Q. 1260?

22          A. Yes. I'm just going to put on the record, this  
23 is clearly deliberative process. And it talks about  
24 OCC, so it's clearly deliberative process when I was not  
25 there, so I would ask you to be cautious.



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1           Q. Don't worry about me. I'll take the risks  
2 associated with asking the question based on a document  
3 that's been turned over to us by the FDA itself.

4           A. I respect that, sir, but you understand this is  
5 clearly deliberative process.

6           Q. No, I don't. I don't. I don't agree with you,  
7 and I'm going to ask you the question. Tell me --

8           A. Let me read the document -- let me read the  
9 whole thing.

10           Yes, sir.

11           Q. Okay. You'll see that the Ota email is dated  
12 June 27th, 2008.

13           A. I do.

14           Q. And you will also see that the text of the Ota  
15 email establishes that there was a warning letter to  
16 NECC on December 4, 2006, and that NECC responded  
17 January 5th, 2007, correct?

18           A. Yes.

19           Q. Now, was it acceptable at the FDA not to  
20 respond to a reply to a warning letter for over a year  
21 and a half? Was that acceptable?

22           MR. ARBITBLIT: Object to form.

23           MR. CHALOS: Object to form.

24           THE WITNESS: Depends the basis for not  
25 replying.

1                   **MR. GIDEON:** Q. What was the basis for not  
2 responding to the NECC reply of January 5th until at  
3 least a year and a half later, sometime after June  
4 27th of 2008?

5                   A. I can speculate if you would like.

6                   Q. Do you know?

7                   A. No.

8                   Q. Okay. Now, was it the policy of the FDA that  
9 when a company received a warning letter and replied,  
10 that FDA would not inspect that company again until the  
11 FDA had provided a written response to the reply?

12                  A. I'm not sure I'm aware of a formal policy like  
13 that.

14                  Q. Was it a -- was it a regulation that provided  
15 that a company that had received a warning letter could  
16 simply eliminate prospective inspections by filing a  
17 reply, and if FDA didn't respond to the reply, they were  
18 free of any inspections from that point forward?

19                  A. No. I don't think that would be accurate at  
20 all.

21                  Q. That's what happened here, though, isn't it?

22                  **MR. ARBITBLIT:** Object to form.

23                  **THE WITNESS:** No, I don't think that's what the  
24 record shows. I think what you see is that there's a  
25 legal tussle that is going on on the jurisdiction of



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1       **FDA.**

2                  In fact, if you look at much of the warning  
3 letter, it really is a -- FDA's letter talks about their  
4 legal authority. Talks about -- I mean, it's really not  
5 relevant to this case. It was about Trypan Blue, there  
6 was some Avastin issues, right?

7                  But so FDA is setting out its legal position.  
8 NECC has its lawyers come back and say FDA, you're  
9 wrong. It cites Gonzalez in there and says you don't  
10 have jurisdiction. We're a compounder. So what is -- I  
11 mean, anybody who looks at this, you actually have --  
12 again, I can't be exactly sure -- her response was in  
13 office of chief counsel.

14                 So if you want to know what was going on,  
15 right, you are going to have to get into the  
16 deliberative process of the FDA, and that's why I'm  
17 asking you to be cautious here.

18                 Q. I've heard that. You heard my response to that  
19 as well.

20                 Do you recall any time, during your tenure at  
21 the FDA, where a company was able to forestall  
22 prospective inspections simply because FDA had never  
23 responded to the company's reply to a warning letter?

24                 A. I'm just trying to think.

25                 I don't know of an analogous situation.

1 Q. All right.

2 A. And I'm not sure I agree with you on your  
3 premise of your question, right, of the company was able  
4 to forestall. That was your conclusion of the facts and  
5 your interpretation. I'm not agreeing with it.

6 Q. Well, let's see if it's me versus the FDA.  
7 Pull out FDA 427667, please.

8 THE WITNESS: How much time is left?

9 MR. GIDEON: Five hours and 47 minutes.

10 THE WITNESS: Thank you.

11 MR. ARBITBLIT: Thirteen minutes left.

12 MS. WEEETER: Which one did you say, C.J.?

13 MR. GIDEON: FDA --

14 MS. WEEETER: 427667?

15 MR. GIDEON: -- 427667. It's October 2, 2008.

16 Make that the next exhibit.

17 (Whereupon, Exhibit 1261 was marked for  
18 identification.)

19 MR. CHALOS: Is this three pages or three  
20 copies?

21 MS. WEEETER: Three copies.

22 MR. GIDEON: Q. You'll see an email  
23 from -- do you know, is it Mutahar Shamsi, am I  
24 pronouncing that correctly? Do you know the  
25 individual in question?



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1           A. I don't believe so.

2           Q. Well, I'm doing the best I can as far as the  
3 pronunciation. I think it is Mutahar Shamsi, to Bruce  
4 Ota. At the top, it's dated October 2nd, 2008.

5           A. Yes.

6           Q. And in the second sentence it says: Regina and  
7 I were insistent that some sort of letter has to go out  
8 before we reinspect.

9                   Do you know of any basis for that in an  
10 operating standard, informal policy and procedure,  
11 statute or regulation that says you can't go back and  
12 look again unless you've responded to a reply to a  
13 warning letter?

14           A. This was not the typical -- so the answer is  
15 no. But this was not the typical warning letter and  
16 response. This was a legal dispute, I mean,  
17 regrettably, between FDA and lawyers for NECC and saying  
18 you don't have jurisdiction, FDA.

19                   If I were in the field, I could certainly say  
20 to headquarters, only be logical, please resolve this.  
21 I'm not walking in there to be told that they don't have  
22 jurisdiction again. Do we have jurisdiction or do we  
23 not have jurisdiction.

24                   So obviously, I mean, I could be sympathetic --  
25 again, I don't know exactly who's who here. But I

1       wouldn't want to walk into a firm where there's a legal  
2       dispute if I were an FDA investigator. That's not fair  
3       to the FDA investigator until they knew whether the  
4       office of the chief counsel was going to support them.

5                   And again, I think we are very close to  
6       deliberative process here.

7       Q. Now, in October of the same year, pulling  
8       FDA 426106 to 107, the same month as this statement that  
9       they're not going to go back until there is a reply to  
10      the response?

11      A. That's not what this says. You  
12     mischaracterized that. It says: CDER is going to try  
13     to set up a conference call with Kevin Fanin and others  
14     at the office of the chief counsel next week to try and  
15     resolve this.

16                   Somebody wants -- I mean, Regina and I were  
17     insistent that some sort of letter has to go out before  
18     we reinspect. They're trying to resolve this with their  
19     colleagues.

20                   (Whereupon, Exhibit 1262 was marked for  
21     identification.)

22      MR. GIDEON: Q. The same month we have the  
23     underlying documents that reflect an outbreak of  
24     klebsiella pneumonia on multiple patients in this  
25     email that is FDA 426106 to 107 in the city of

1      New York. Correct?

2                At least 5 and up to 17 individuals exposed to  
3      klebsiella pneumonia. Three hospitalized, two with  
4      positive blood cultures, nine have been interviewed  
5      without symptoms. Symptoms -- or the exposure occurred  
6      between October 13th and 14th. The patients received an  
7      intravenous version of the drug triamcinolone, brand  
8      name Kenalog, made by NECC.

9                A. Could you kindly pull NECC\_FDA 08550, and then  
10     zero -- 03476 on October 28th? What's the date of  
11     these?

12               If you can give me the October 28th documents.  
13     Go ask your question, but let's pull those documents.  
14     Ask your question.

15               MS. WEETER: What was the first number you  
16     said?

17               THE WITNESS: NECC\_FDA 08550. Then I think it  
18     is 03476, but I could be wrong. But you should have it.  
19     One is an October 30th document, and one is an October  
20     28th document.

21               But go ahead, ask your question.

22               MR. GIDEON: Q. Well, doesn't this  
23     document establish that there was a product made by  
24     NECC that was used on multiple patients? Question.

25               A. That's correct.

1 Q. Yeah.

2 A. But that's not -- I mean, but please do the  
3 full record here. I believe FDA went to the pain clinic  
4 and decided the pain clinic -- let's find the documents,  
5 but let me have them in front of me.

6 I believe FDA went and inspected the pain  
7 clinic and found the pain clinic did not have proper  
8 infectious control practices and the problem was at the  
9 pain clinic. But please pull those documents so we can  
10 have those on the record.

11 Q. Isn't this correct, though, you had a number of  
12 people sick, FDA knew that there was product being made  
13 and sold by NECC without patient-specific prescriptions,  
14 as confirmed by the documents that are right in front of  
15 you.

16 A. So, again --

17 Q. Simple question. Is that true or not?

18 A. So let's just -- so just give me the line. I  
19 haven't read this. Tell me where it says that. I'm  
20 sure you are right, but just give me the line where it  
21 says that.

22 Q. Well, bullet point one: At least five and  
23 possibly up to 17 individuals exposed to klebsiella  
24 pneumonia.

25 A. Yes.

1 Q. Bullet point four, it was made by NECC.

2 Triamcinolone, also known as Kenalog.

3 A. Right.

4 Q. Correct?

5 A. Again, I think there's some question about the  
6 NECC product in the subsequent documents, but I'm not  
7 going to -- you know, I need those documents in front of  
8 me before testifying.

9 Q. Doesn't establish that there were not  
10 patient-specific prescriptions --

11 A. Show me where --

12 Q. -- covering --

13 A. -- says that --

14 Q. -- the product used on multiple patients?

15 MR. CHALOS: Object to form.

16 THE WITNESS: I'm sorry. Show me where it says  
17 that, please.

18 MR. GIDEON: Q. The bottom of the first  
19 page.

20 A. The triamcinolone was provided in a 10  
21 multi-vial -- right? The envelope had on it a  
22 prescription --

23 Q. No, no, no. Don't skip it. Read it very  
24 carefully. The envelope reportedly had on it --

25 A. Reportedly had on it --



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(Reporter requests one speaker at a time.)

MR. GIDEON: I'll read it. Quote: The envelope reportedly had on it a "prescription" for a single patient being seen at the clinic.

The clinic drew multiple doses from this single-patient-specific-vial and used this for several patients.

Doesn't that establish there were not patient-specific prescriptions for each administration of the NECC product?

A. This certainly seems to be exactly what it says. It seems to be -- there was a vial with a prescription, okay, I mean, on it, for one patient. And it looks like somebody reused this for multiple patients.

And to be honest with you, I think you have your answer on the klebsiella. Because why is somebody using a single unit for multiple patients. So somebody at the pain clinic obviously doesn't know basic infection control, but let's take a look those documents.

Q. Well, the vial doesn't have a prescription on it. The vial doesn't say anything about being for a specific patient.

#### A. The envelope did.



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1           Q. The envelope reportedly had on it a  
2 prescription.

3           A. It says exactly what it says.

4           Q. Correct. Which is why I asked the question.  
5 Doesn't this make it clear, didn't FDA know that NECC  
6 was selling product that was not being used for specific  
7 patients?

8           MR. CHALOS: Object to the --

9           MR. GIDEON: Q. And not being subject to  
10 patient-specific prescriptions?

11          MR. CHALOS: Object to the form. Misstates the  
12 document.

13          MR. GIDEON: Argumentative.

14          Go ahead.

15          THE WITNESS: This --

16          MR. CHALOS: Object to the commentary.

17          THE WITNESS: And can I see my documents that I  
18 requested, please, if you can help me?

19          MS. WEEETER: They're on my computer. I can  
20 read them. Do we need to read those or do we want to  
21 move on?

22          MR. GIDEON: Q. I'm going to give  
23 Dr. Kessler the opportunity to explain why you need  
24 the documents. And if you can tell us why we should  
25 spend time on it we'll do it for you. But just to



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1 request the documents to talk about them isn't  
2 really pertinent.

3 A. So you don't -- you're not asking -- you didn't  
4 ask what -- whether FDA acted appropriately on this?

5 Q. No. I've already asked you some questions --

6 A. And I --

7 Q. I'm certain you're going to say that FDA acted  
8 in the highest standards of regulatory oversight. I  
9 expect that.

10 MR. CHALOS: Objection. Argumentative.

11 MR. ARBITBLIT: For completeness, I'll read  
12 from the document that the witness referred to, which is  
13 an October 30, 2000 email from Robert Durkin to Samia  
14 Nasr saying: It seems it was lack of aseptic technique  
15 at the clinic level with subsequent contamination of the  
16 Visipaque --

17 (Reporter clarification.)

18 MR. ARBITBLIT: -- Visipaque -- capital  
19 V-I-S-I-P-A-Q-U-E -- manufactured by GE Healthcare, end  
20 of quote.

21 And the page number of that -- and that's  
22 responding to a question from Nasr to Durkin on the same  
23 date. And the question is, quote: It looks like they  
24 ruled out that the problem was from NECC, triple  
25 question mark, end of quote.

1                   So your attempts are --

2                   MR. GIDEON: Q. We'll make that the next  
3 exhibit. Does that reflect --

4                   MR. ARBITBLIT: Hold on.

5                   MR. GIDEON: -- the presence --

6                   MR. ARBITBLIT: I'll read the number so you can  
7 find it. It's NECC\_FDA 08550, which is part of an  
8 11-page document.

9                   MR. GIDEON: Q. Does that reflect the  
10 presence of testing on the vial?

11                  A. I have to see the -- you have to give me the  
12 document.

13                  Q. Does it reflect testing on the vial?

14                  A. Sounds like it's not an NECC product.

15                  MS. WEETER: It is an NECC --

16                  THE WITNESS: What?

17                  MS. WEETER: They received an NECC product.

18                  THE WITNESS: I'm sorry?

19                  MR. GIDEON: Q. Does it reflect testing on  
20 the vial?

21                  THE WITNESS: Could someone print that?

22                  MR. ARBITBLIT: Object to form. What vial?

23                  MR. GIDEON: The vial that we've spent five  
24 minutes talking about. The multi-use vial with  
25 triamcinolone in it made by NECC.



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1 I'm just asking --

2 THE WITNESS: Can I see that document?

3 MR. CHALOS: It's on the screen.

4 MR. GIDEON: I'm just asking, Kaycee, does it  
5 reflect testing on the vial?

6 MS. WEETER: It looks like they requested  
7 samples or reports from the New York NYC DHMH, and  
8 there's no evidence in here that they had results from  
9 those --

10 MR. GIDEON: Hmm.

11 MS. WEETER: -- samples that were --

12 THE WITNESS: It does say these have been sent  
13 to the department's labs.

14 MR. GIDEON: Q. Is there anything in there  
15 reflecting that what you told me earlier should  
16 occur, which is, you go ahead and you look at this  
17 material, you get the laboratory data and determine  
18 what's in the product to see if it relates to the  
19 illness of the patient? Do you find any reflection  
20 of testing of the vial?

21 A. Yes. You see it says here, these have been  
22 sent to the department's labs.

23 Q. What's the result?

24 A. I'm sorry, you have to give me the record if  
25 you want me --



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1           Q. Well, I suspected, since you asked for the  
2 documents earlier, you would have looked yourself to see  
3 if the vial was tested.

4           A. Hold on one second.

5           Q. And that's the pending question: Was the vial  
6 tested to see if it was contaminated?

7           A. Let me just read this.

8           MR. ARBITBLIT: Counsel, I think we're at the  
9 end of seven hours. In the spirit of cooperation, if  
10 the witness is willing, we'd like you to have an  
11 additional 15 minutes. You probably aren't going to  
12 think that's sufficient, I'm guessing, because we never  
13 seem to agree on that. But that's what we're offering.  
14 If you would like to continue with the questioning for  
15 an additional 15 minutes, we're willing to stay for  
16 that.

17           MR. GIDEON: Well, I'm happy to take the  
18 additional 15 minutes, but it won't be sufficient to  
19 complete what I intend to do today. So if -- I'll take  
20 the 15, but not with the agreement that that's it.

21           MR. ARBITBLIT: I wasn't asking for your  
22 agreement. I wasn't expecting it.

23           MR. GIDEON: What I want to understand is can I  
24 go ahead and take the extra 15, then seek permission  
25 from the magistrate to complete this deposition, or is

1 the 15 a "if you take this you have agreed that that's  
2 it"?

3 MR. ARBITBLIT: No, I was not suggesting 15  
4 minutes and you are forever barred. You can seek what  
5 you want and we'll oppose it, and we think we're being  
6 reasonable.

7 MR. GIDEON: I appreciate the 15 minutes. Very  
8 gracious.

9 MR. CHALOS: Would 30 minutes obviate your  
10 concern?

11 MR. GIDEON: No. I think Dr. Kessler's lack of  
12 response to literally every question today has made it  
13 such that I've really had just a couple hours to  
14 actually ask him questions. It has been a long time  
15 since I've seen a witness this unresponsive, so I will  
16 be seeking additional time. And we'll use examples from  
17 today's deposition to attempt to convince the judge to  
18 let us have that time.

19 MR. ARBITBLIT: I expect that you will. And  
20 we'll probably use examples of your improper questioning  
21 in response.

22 MR. GIDEON: Sure. Well, I don't know what  
23 we're doing right now. He's looking at something, I  
24 don't know why, I don't know what he intends to do.

25 THE WITNESS: You have a question pending, sir.

1                   MR. GIDEON: Q. Well, I asked you did they  
2 ever test the vials, which you told us was the gold  
3 standard for a response by the regulator.

4                   MR. CHALOS: Object to the form.

5                   MR. ARBITBLIT: Object to form.

6                   MR. GIDEON: Q. What is the answer to that  
7 question?

8                   A. Yes, this was tested. I'm just trying -- this  
9 was tested and I'm just trying to understand.

10                  Q. What were the results, then?

11                  A. I don't have the results in this document, but  
12 this was sent for testing.

13                  Q. I know --

14                  A. And it was concluded that there were improper  
15 infection control practices at the clinic.

16                  Q. Okay.

17                  MR. ARBITBLIT: May I have the computer back  
18 now?

19                  THE WITNESS: Thank you.

20                  MR. GIDEON: Q. Now, take a look at the  
21 exhibit that reflects the materials produced by FDA.  
22 The larger document that has the time line, the  
23 chronology that's typed.

24                  A. Yes, sir.

25                  Q. Can you give me the exhibit number on that

1 again, please

2 A. 424316.

3 Q. No, no, no. The exhibit number. Remember,  
4 it's on the back of the first page.

5 A. Sure. 1258. 1258.

6 Q. Okay. If you will look at the next page,  
7 September of 2009, your former employer receives  
8 complaints about NECC mass producing and distributing  
9 sodium tetradecyl sulfate and erythromycin ointment  
10 without patient-specific prescriptions.

11 There is no record that FDA did a thing about  
12 that in response?

13 A. Could you show me those complaints.

14 MS. WEETER: This is based on the document that  
15 was produced by the FDA. I'm not --

16 MR. GIDEON: Q. They didn't identify what  
17 the basis for this was.

18 A. I'm not sure this document was produced by FDA.

19 Q. It was produced --

20 MS. WEETER: It's Bates stamped by the FDA.

21 THE WITNESS: It was produced by FDA, but I'm  
22 not sure it was prepared by the FDA.

23 I have no record of what this is. And if you  
24 want to give me what this is, happy to look at it.

25 MR. GIDEON: Q. I'm going to ask you



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1       questions about what should have happened, given  
2       your expertise in regulation.

3                  With this background with NECC, if FDA received  
4       complaints about NECC mass producing and distributing  
5       sodium tetradecyl sulfate and erythromycin ointment  
6       without patient-specific prescriptions, what should FDA  
7       have done?

8                  MR. CHALOS: Object to the form. Incomplete  
9       hypothetical.

10                 THE WITNESS: You are asking my personal  
11      opinion?

12                 MR. GIDEON: Q. No, no. I'm asking you as  
13      the expert that you say you are in regulation of  
14      pharmaceuticals and as a person who has worked as a  
15      regulator. I don't want just an off-the-cuff  
16      personal opinion, I want the opinion you think you  
17      are qualified to offer as an expert.

18                 MR. CHALOS: Let me interpose an objection.  
19      I'm not sure it relates to his opinions he's given in  
20      this case. Is there something specific in his report  
21      that you are tying this to? Otherwise this is just  
22      asking him on the fly to create a new opinion based on a  
23      sentence that has no backup with any document. So I  
24      object to the questioning here.

25                 MR. GIDEON: Q. Go ahead.

1           A. So --

2           Q. No, no. Here's the question.

3           A. Okay.

4           Q. With that data, FDA, with this background,  
5 receives complaints that NECC is mass producing and  
6 distributing sodium tetradecyl sulfate and erythromycin  
7 ointment without patient-specific prescriptions. As an  
8 expert in regulatory oversight, what should FDA have  
9 done?

10           MR. CHALOS: Same objection and incomplete  
11 hypothetical.

12           THE WITNESS: I can tell you what I wish FDA  
13 had done.

14           MR. GIDEON: Q. I want to know what they  
15 had a responsibility to do.

16           MR. CHALOS: Same objections.

17           THE WITNESS: In 2009, it's not clear that FDA  
18 had any responsibilities except other than when you're  
19 dealing with contaminated substances. The law was  
20 unclear. FDA acted each and every time when there was  
21 evidence of contamination.

22           The regulatory and legal status of NECC was  
23 being fought back and forth by lawyers. Some in the  
24 pharmacy industry saw, as you saw in those articles,  
25 that FDA was very aggressive and too aggressive in light

1 of what they viewed the law was, right?

2 So I mean, if there was harm, if there was  
3 samples that were positive, FDA should have acted. I  
4 would have -- I certainly would have wished that FDA had  
5 gone in and exposed this scheme about false  
6 prescriptions. That's what I wish. But you can't -- I  
7 don't think anybody could say credibly, with the varying  
8 law and the confusion at that time, right, with the --  
9 in the absence of public health evidence, regrettably,  
10 that was the standard of the filthy, putrid -- that was  
11 what FDA really had available to it. And that's what  
12 FDA should use.

13 Public health, should act. Just on patient  
14 prescriptions, there's a fight. There's a fight on what  
15 the interpretation of the law is. I wished FDA had  
16 closed down this whole scheme that was going on, NECC,  
17 later on STOPNC, anyone else.

18 Q. Who were they scheming with in 2009? "They,"  
19 being NECC.

20 A. You have to give me the documents for 2009.  
21 I've asked for them, right? So there was scheming going  
22 on. There was this scam going on, and it certainly went  
23 on with your client too, right? And I wish FDA and the  
24 state boards had closed that down.

25 Q. Was FDA scheming, too, to look the other way

1       when told product was being shipped without patient  
2       specific -- let me finish. Was FDA scheming with NECC,  
3       looking the other way when told that there were no  
4       patient-specific prescriptions, but they looked the  
5       other way as part of a scheme?

6                    MR. CHALOS: Object to the form.

7                    THE WITNESS: No. No. FDA -- Congress took  
8       away FDA's authority in 1997 of the new drug provisions.  
9       The industry sued FDA, I mean, at least three times, if  
10      not more. Every time FDA acted, right, it was met with  
11      a barrage.

12                  To criticize FDA, right, I mean, if you -- you  
13      know, it's -- only in this country can you take away  
14      FDA's authority and then go where was FDA when somebody  
15      gets hurt. That doesn't make sense, sir. Right?

16                  I mean, there were responsibilities, right, to  
17      have prescriptions. Your client had their  
18      responsibility, NECC had that responsibility, right, and  
19      had that happened, we wouldn't be -- been people  
20      following that, we wouldn't be sitting here. There was  
21      a scam. FDA's authority was taken away in 1997.

22                  Q. So from and after 1997, the FDA was impotent by  
23      virtue of law to take any action to protect the public  
24      from compounders?

25                  A. That's not what I said.

1                   **MR. ARBITBLIT:** Misleading. Mischaracterizes.  
2 Argumentative.

3                   **THE WITNESS:** I was very clear that if there  
4 were contaminated samples that FDA had, right, under  
5 501, right, FDA could act. That was clear. And FDA did  
6 that each and every time. The issue of shipment and  
7 interstate commerce of compounded drugs, right, that,  
8 there were great legal battles going on, right?

9                   **MR. GIDEON:** Q. So from 1997 forward,  
10 instead of the FDA, if the state Board of Pharmacy  
11 or state Department of Health did not enforce the  
12 patient-specific prescription requirement, then it  
13 was up to the purchasers to do so, but not the FDA?

14                  A. You --

15                  **MR. CHALOS:** Object to the form.

16                  **THE WITNESS:** You certainly have -- I mean, in  
17 the record I think I have it somewhere I could pull it.  
18 I know time is short. You have certain clinics  
19 complaining to their state boards about this, where they  
20 would not engage in this kind of conduct. So you do see  
21 the reporting by clinics in the same position as STOPNC  
22 and saying we shouldn't do this and complain to their --  
23 to their boards.

24                  **MR. GIDEON:** Q. Do you recall being  
25 provided with a copy of a complaint that came out of

1       Nashville by Clint Ebel (phonetic) against NECC?

2           A. I have to double-check, sir.

3           Q. Does that ring a bell? Were you provided with  
4 a copy of the Ebel deposition? Look and see if that's  
5 something you got.

6           A. Let me see if I got it -- I looked at it.

7           Yes, I do have the Ebel deposition. I'm not  
8 sure how much time I spent with it. Give me the  
9 exhibit.

10          Q. I'm going to give it to you in just a second.

11          A. Thanks.

12           MR. ARBITBLIT: Counsel, I think this will be  
13 the last document we have time for pursuant to the  
14 agreement.

15           MR. GIDEON: Exhibit No. 25.

16           THE WITNESS: I have different exhibit numbers.

17           MR. GIDEON: No, no. It's our internal list so  
18 we can pull these materials.

19           THE WITNESS: I'm sorry.

20           MR. ARBITBLIT: While she's pulling that, just  
21 to save time I want to -- one more completeness item  
22 which is from NECC\_FDA 02655 and 2656, which is a  
23 correspondence between FDA's Robert Kang and Samia Nasr  
24 referring to the klebsiella infections issue which  
25 states, quote: The evidence points to problems with



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1       infection control procedures at the clinic. The  
2       New York lab is growing klebsiella from an open vial of  
3       contrast that they got from the facility. And attaches  
4       at the second page of the document a reference from  
5       Marcell Layton (phonetic), M.D., Assistant Commissioner  
6       Bureau of Communicable Disease for the New York City  
7       Department of Health stating Argen (phonetic), our lab  
8       just notified us that the bottle of iodixanol,  
9       I-O-D-I-X-A-N-O-L, (was an open bottle used on about 15  
10      patients) is growing a klebsiella, K-L-E-B-S-I-E-L-L-A.  
11      We wanted to notify you, and through you, appropriate  
12      folks at FDA, end of quote.

13                    MR. GIDEON: Q. Before we handed you this  
14      document, were you aware of the fact that in June of  
15      2008, Clint Pharmaceuticals based in Old Hickory,  
16      Tennessee, which is part of the Middle Tennessee,  
17      complained directly to the FDA about product being  
18      made by NECC and being sold in that market?

19                    A. I don't believe I -- I have no recollection of  
20      this. But obviously I have it. I mean, but I did not  
21      spend a lot of time with the Ebel deposition.

22                    Q. Okay. What did accepted standards require of  
23      the FDA when you have a company like Clint  
24      Pharmaceuticals complaining about NECC marketing product  
25      without patient-specific prescriptions and not in

1 limited volume?

2 (Whereupon, Exhibit 1263 was marked for  
3 identification.)

4 MR. ARBITBLIT: Object to form.

5 MR. CHALOS: Object to the form.

6 MR. ARBITBLIT: And we'll call that the last  
7 question for today.

8 THE WITNESS: Show me where you are referring  
9 to, sir.

10 MR. GIDEON: Q. No, just answer the  
11 question since it is the last one.

12 A. Let me read the documents.

13 Q. What did the standards require of the FDA when  
14 you have a member of the public, informed member,  
15 complaining about NECC's conduct in their business  
16 market --

17 MR. CHALOS: Object to the form -- I'm sorry.

18 MR. GIDEON: Q. -- June 17th, 2008, what  
19 was expected of the FDA under these circumstances?  
20 Reasonably expected of the FDA under those  
21 circumstances?

22 MR. CHALOS: Object to the form. Misstates the  
23 document. Misstates the facts.

24 THE WITNESS: Let me take a look at it. Could  
25 you point to me -- I'm looking at this document. Just



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1 show me the NECC part.

2 MR. GIDEON: Q. Down at the bottom.

3 A. Which one?

4 Q. It's on the memorandum. See the memorandum  
5 section?

6 A. The second page? Yeah?

7 Q. It's actually the third.

8 A. Third page. So -- because he's complaining  
9 about a number of different compounds.

10 Q. Yes.

11 A. Is that correct?

12 Q. Yeah. But he's complaining about the -- he is  
13 complaining about NECC, as you can see at the bottom.

14 A. Let me just see. So this is on the June 18th?  
15 Is that the paragraph that I should be reading?

16 Q. June 17th, 2008. At the bottom it says three  
17 additional vials.

18 A. I'm on the same page. Give me the Bates  
19 number.

20 MR. CHALOS: That's the right page.

21 MR. GIDEON: Q. 434734.

22 A. On June 18th.

23 Q. Yeah.

24 A. On June 18th I contacted --

25 Q. It says at the bottom, to answer your

1 question --

2 A. Thank you.

3 Q. -- three additional vials were received from  
4 the gentleman, which were three sizes of betamethasone  
5 manufactured by New England Compounding Company.

6 MR. CHALOS: I think what he's saying is the  
7 first part of that paragraph says on June 18th.

8 MR. GIDEON: Q. Yes. Yeah, that's right.

9 A. Okay. I'm sorry.

10 If I'm reading this correctly, correct me if  
11 I'm wrong, he's defining the compounding is going on,  
12 right, of betamethasone, correct? That's the way I read  
13 this, sir. He's saying here's three examples of  
14 compounding. You asked me what the standard was?

15 Q. What response was reasonably to be expected  
16 from the FDA with this complaint from Clint  
17 Pharmaceuticals?

18 A. Well, again --

19 MR. CHALOS: Object to the form.

20 THE WITNESS: -- you have multiple -- multiple  
21 complaints about multiple compounders. And again, what  
22 is responsible is if there was a public health hazard  
23 for contaminated product after -- you know, the law  
24 allowed these guys to compound, right? There was great  
25 debate on what that -- how that would be defined.



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1                   FDA, at this point, had its authority stripped,  
2 and the circuits added confusion. And FDA has a  
3 responsibility if there was -- somebody was being  
4 harmed -- for example, like the klebsiella example, that  
5 ended up not being an NECC product, I mean, apparently,  
6 that was infected, according to the document that was  
7 just read. So if there's a New England Compounding  
8 product that's contaminated -- that contamination is  
9 causing injury, FDA certainly should have been in there.

10                 Regrettably, okay, when that evidence of  
11 contamination occurred, because that was the authority  
12 that was left by Congress, when that authority -- when  
13 that was found, a lot of people were already hurt.

14                 MR. ARBITBLIT: And with that, we are going to  
15 close for the day. I would just like --

16                 THE WITNESS: I have two -- I have one or two  
17 things just to -- I'd like to just put on the record.

18                 MR. ARBITBLIT: Go ahead.

19                 THE WITNESS: So I just want to clarify one  
20 issue. You asked me about my list that I've testified,  
21 remember the cases I've testified and Lieff Cabraser,  
22 their involvement, and we did all the cases that I  
23 testified.

24                 But then when you got to the bottom, I think I  
25 identified those appropriately, there may be one of

1 those cases in DePuy, that declaration, I'd have to  
2 check my memory that Lieff Cabraser was involved in.  
3 And just -- so I just wanted to add that for the record.

4 And I also just want to add for the record,  
5 just so it's clear, that nothing that -- in my  
6 conversation with that senior FDA official that I did  
7 not name, I did not in any way rely on that person for  
8 any of my opinions.

9 MR. ARBITBLIT: Thank you, Doctor.

10 We would request the rough draft as soon as  
11 possible. I don't know what the procedure has been for  
12 expediting or not expediting. Not expediting. Okay.

13 MR. GIDEON: Well, she said she can get it done  
14 by --

15 MS. MARTINEZ: We wanted it expedited.

16 MR. GIDEON: Didn't you say you could get it  
17 done by Tuesday? That should be satisfactory.

18 MR. CHALOS: Well, we need a rough to send to  
19 the government.

20 MR. ARBITBLIT: If you're willing to wait for  
21 the final to go to David Glass for his one-day 24-hour  
22 review, then we'll wait for the final on Tuesday.

23 MR. GIDEON: Are you still running the video?

24 THE VIDEOGRAPHER: Uh-huh.

25 MR. GIDEON: We can go off the video and do

1       this on the transcript. Is that all right with you?

2           MR. ARBITBLIT: That's fine

3           THE WITNESS: May I be excused?

4           MR. GIDEON: Of course you can. Make sure you  
5 take your mic off.

6           THE WITNESS: I'm not taking any documents, I'm  
7 just going to the men's room. Thank you, sir.

8           THE VIDEOGRAPHER: This is the end of today's  
9 deposition. We are off the record at 5:41 p.m.

10          The master disc will be held by Discovery  
11 Litigation Services.

12          MR. GIDEON: Don, dictate what you propose to  
13 do about the --

14          THE REPORTER: Still on the record, though?

15          MR. GIDEON: Still on the record with you.

16          MR. ARBITBLIT: My proposal is, since the court  
17 reporter has graciously agreed to provide a final  
18 transcript on Tuesday, if I'm correct -- correct me if I  
19 say anything that is wrong, I'm sure someone around the  
20 table will -- that --

21          MR. GIDEON: Objection. Misleading.

22          MR. ARBITBLIT: Argumentative.

23          MR. GIDEON: Argumentative.

24          Go ahead.

25          MR. ARBITBLIT: Are you sure your name isn't

1 J.C.?

2 MR. GIDEON: It's actually Clarence. Clarence  
3 James.

4 MR. ARBITBLIT: Clarence James. Thank you. I  
5 was wondering.

6 So my proposal is that since we could get the  
7 final by Tuesday, that we give David Glass a break.  
8 Because I was looking at some of the very clever  
9 transcription shorthand, like the word, three syllables,  
10 one of which was "yum." I don't remember what the word  
11 was, but it struck me that that was not -- moratorium --  
12 that's what it was -- mor-tor-yum -- that we give David  
13 Glass an extra two days. One -- instead of Monday, it  
14 would be Tuesday for him to get the transcript,  
15 Wednesday for him to tell us whether he has any problems  
16 with it.

17 And then during that time, we would refrain  
18 from sharing the transcript with other experts. Because  
19 I think that would be consistent with David Glass'  
20 request that we keep it sealed until he has a chance to  
21 look at it.

22 MR. GIDEON: I can't agree to that with respect  
23 to other experts. I can agree as to dissemination  
24 beyond our experts and the lawyers. I can agree not to  
25 disseminate it to our clients, but I can't -- cannot

1 agree with respect to other experts.

2 MR. ARBITBLIT: And you -- will you agree to  
3 instruct your other experts that the document, meaning  
4 the transcript, is going to be reviewed by counsel for  
5 the USA and that they should not disclose what's in it  
6 to anybody except you and your staff --

7 MR. GIDEON: Yes.

8 MR. ARBITBLIT: -- until David Glass has a  
9 chance to respond?

10 MR. GIDEON: I will agree to that.

11 MR. ARBITBLIT: Okay. And we'll wait, then.  
12 Do you know -- what's your best estimate as to when on  
13 Tuesday we might receive it?

14 THE REPORTER: I'm planning to turn it into the  
15 reporting office in the morning, the beginning of the  
16 business day. So it depends on how long it takes them  
17 to turn it around. I can tell them to --

18 MR. ARBITBLIT: The beginning of the day on  
19 Tuesday?

20 THE REPORTER: On Tuesday.

21 MR. ARBITBLIT: Are there any spellings we can  
22 help you with?

23 MR. CHALOS: Klebsiella?

24 THE REPORTER: You actually spelled that.

25 But there are other things, for instance,



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1       there's a hard drive with a sticker on it, and I need to  
2       know what the agreement is on that.

3                  MR. GIDEON: The agreement on that was to  
4       transfer it digitally.

5                  MR. ARBITBLIT: That's fine.

6                  THE REPORTER: So I need to know if that's  
7       going to be retained by counsel. That's fine.  
8       Otherwise they don't like to release the transcript  
9       without the complete exhibits.

10                 MR. CHALOS: We can make a photocopy of this  
11      right now so you can have something to put in there.

12                 THE REPORTER: Yeah, that's fine. As long as I  
13      am not supposed to have the contents of the hard drive  
14      attached.

15                 MR. CHALOS: I can make a photocopy of this and  
16      you can say "retained by counsel."

17                 THE REPORTER: That's fine. And then what  
18      about the blotter?

19                 MR. GIDEON: I'd like to make the blotter as  
20      the next sequential exhibit, but we'll agree to keep a  
21      copy as the exhibit and you can have your original  
22      blotter back.

23                 THE REPORTER: So will that be retained by  
24      counsel or sent to the reporting office? Because that  
25      will need to be delivered by Tuesday morning.

1 MR. GIDEON: I don't want to bollix up getting  
2 access to the transcript based on trying to get this  
3 copied. So why don't we provide that the blotter will  
4 be retained by counsel.

5                   Don, can you provide us with the copy of his  
6 blotter at my expense and we'll make the copy the next  
7 exhibit?

8 MR. ARBITBLIT: Yes.

9 MS. WEEETER: And that will be No. 1264.

10 THE REPORTER: And that's the last exhibit for  
11 the day?

12 MR. GIDEON: Yes.

13 THE REPORTER: And 1264 will be retained by  
14 counsel, then, unless we receive it by Tuesday.

15 (Whereupon, Exhibit 1264 was marked for  
16 identification.)

17 MR. ARBITBLIT: Are we off the record?

THE REPORTER: Anything else for the record?

19 MR. GIDEON: No, not that I can think of.

20 (The deposition adjourned at 5:48 PM)

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1           I, Gina V. Carbone, Certified Shorthand  
2 Reporter licensed in the State of California, License  
3 No. 8249, hereby certify that the deponent was by me  
4 first duly sworn and the foregoing testimony was  
5 reported by me and was thereafter transcribed with  
6 computer-aided transcription; that the foregoing is a  
7 full, complete, and true record of said proceedings.

8           I further certify that I am not of counsel or  
9 attorney for either of any of the parties in the  
10 foregoing proceeding and caption named or in any way  
11 interested in the outcome of the cause in said caption.

12           The dismantling, unsealing, or unbinding of the  
13 original transcript will render the reporter's  
14 certificates null and void.

15           In witness whereof, I have hereunto set my hand  
16 this day: March, 8th 2016.

17           \_\_\_\_\_ Reading and Signing was requested.

18           \_\_\_\_\_ Reading and Signing was waived.

19           \_\_\_\_X\_\_\_\_ Reading and signing was not requested.

21           Gina V. Carbone

23           GINA V. CARBONE

24           CSR 8249, RMR, CRR, CCRR



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NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY  
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